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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 293 and 351

Reduction In Force Ratings for Retention-Longer Period to Credit Ratings; Clarification of Assignment Rights

AGENCY: Office of Personnel Management.

ACTION: Final rulemaking.

SUMMARY: The Office of Personnel Management (OPM) is issuing final retention regulations that will allow employees to receive retention service credit for performance ratings received during the 4-year period prior to the date the agency issues reduction in force notices. Under the applicable former regulations, employees received additional service credit for reduction in force purposes based on ratings received during the 3-year period prior to the date the agency issued specific reduction in force notices. The new regulations better ensure that employees competing for positions under OPM's reduction in force regulations receive credit for three actual annual performance ratings. These final regulations also make technical changes in how agencies (1) document the performance ratings that are used for retention purposes, (2) establish competitive areas that cover an Inspector General activity, and (3) offer temporary positions under OPM's reduction in force regulations.

EFFECTIVE DATE: January 16, 1992. For reduction in force actions effective after January 16, 1992, but before January 19, 1993, agencies may use either 5 CFR 351.504 in these final regulations, or the current 5 CFR 351.504 in 5 CFR part 351 (January 1, 1991, edition).

FOR FURTHER INFORMATION CONTACT: Thomas A. Glennon or Edward P. McHugh, (202) 606–0960; FAX (202) 606–0390.

SUPPLEMENTARY INFORMATION:

Summary of Comments

On May 8, 1991, OPM published (at FR 21332) proposed regulations to revise 5 CFR part 351. These regulations proposed: (1) Extending the 3-year period for crediting performance ratings used for retention purposes to a 4-year period; (2) establishing separate competitive areas that cover an Inspector General function; and (3) limiting offers of assignment to temporary positions.

We received comments from seven agencies and one individual. Five agencies and the individual supported our proposal to base reduction in force service credit for performance upon a 4-year period rather than the present 3-year period. One agency did not support the proposal. In the final regulations, we extend the 3-year period to a 4-year period.

One agency also suggested that we publish conforming changes in 5 CFR part 293 (Personnel Records) at the same time that final 5 CFR part 351 regulations are published. We agree with this suggestion and have adopted it in the final regulations.

Two agencies suggested that we clarify that an agency must establish a separate competitive area for an Inspector General activity only if it is established under authority of the Inspector General Act of 1978 (Pub. L. 95–452), as amended. Again, we agree with this suggestion and have adopted it in the final regulations.

Implementation of New Reduction in Force Performance Rating Requirements

To minimize administrative difficulties, the new 4-year period for crediting performance ratings used for retention purposes is being phased in over a 1-year period. It must be applied to any action under 5 CFR part 351 that is effective on or after 1 year following the effective date of these final regulations. In the interim, agencies may use either these final regulations or the present regulations found in 5 CFR 351.504.

(1) Sections 293.404(a)(1) and 293.405(a) are revised to provide that agencies will generally retain performance ratings and supporting documents for a minimum of a 4 years rather than 3 years.

(2) Sections 351.504(b) and 351.504(c) are revised to provide that an employee's entitlement to additional service credit for reduction in force purposes is based on the employee's three most recent annual performance ratings of record received during the 4-year period prior to the date the agency issues reduction in force notices. These final regulations also provide that, when a cutoff date is used, employees receive performance credit for retention purposes based on the three most recent annual ratings received during the 4-year period prior to the cutoff date. In addition, these regulations require that the awarding of additional service credit for reduction in force purposes must be uniformly and consistently applied by an agency, must be consistent with the agency's performance management system, and must be documented in the agency's performance appraisal system.

(3) Section 351.402(d) is added and states that each Inspector General office established under authority of the Inspector General Act of 1978 (Pub. L. 95–452) must be in a separate reduction in force competitive area that is established only for that office.

(4) Section 351.701(a) is revised to clarify longstanding OPM policy that promotion potential is not a consideration in determining whether an employee is offered assignment to another position, and an employee who accepts an offer of assignment retains the same status and tenure in the new position.

(5) Section 351.703 is revised to provide that an agency may waive qualifications in offering an employee assignment only to a vacant, rather than an occupied, position.

(6) Section 351.704(d) is added to prohibit an agency from offering a competing employee assignment to a temporary position except in lieu of separation by reduction in force. This revision provides that an agency may satisfy a nontemporary employee's right of assignment under the reduction in force regulations only by offering the employee a nontemporary position. Also, § 351.704(a)(2) is revised to clarify when an agency may offer a vacant other-than-full-time position to a full-time employee, or offer a full-time position to an other-than-full-time employee.

(7) Section 351.802(a) is revised to provide that an employee's reduction in force notice must include the employee's annual performance ratings of record for retention purposes that the employee received in the 4 years prior to, as appropriate, the date the agency issues reduction in force notices or the agency's cutoff date, as covered in § 351.504.

E.O. 12291 Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects Federal employees.

List of Subjects in 5 CFR Parts 293 and 351

Government employees.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM is amending parts 293 and 351 of title 5, Code of Federal Regulations, as follows:

PART 293—PERSONNEL RECORDS

1. The authority citation for part 293 continues to read as follows:

Authority: 5 U.S.C. 552, 4302a, and 4315; E.O. 12107 (December 28, 1978); 3 CFR 1954–1958 Comp.; U.S.C. 1103, 1104 and 1302; 5 CFR 7.2; E.O. 9830; 3 CFR 1943–1948 Comp.; 5 U.S.C. 2951(2) and 3301; and E.O. 12107.

2. Section 293.404(a)(1) is revised to read as follows:

§ 293.404 Retention schedule.

(a)(1) Except as provided in § 293.405(a), performance ratings or documents supporting them are generally not permanent records and shall, except for appointees to the SES and including incumbents of executive positions not covered by SES, be retained as prescribed below:

(i) Performance ratings of record, including the performance plans on which they are based, shall be retained for 4 years;

(ii) Supporting documents shall be retained for as long as the agency deems appropriate (up to 4 years);

(iii) Performance records superseded (e.g., through an administrative or judicial procedure) and performance-related records pertaining to a former employee (except as prescribed in § 293.405(a)) need not be retained for a minimum of 4 years. Rather, in the former case they are to be destroyed and in the latter case agencies shall determine the retention schedule; and

(iv) Except where prohibited by law, retention of automated records longer than the maximum prescribed here is permitted for purposes of statistical analysis so long as the data are not used in any action affecting the employee when the manual record has been or should have been destroyed.

* * * * *

3. Section 293.405(a) is revised to read as follows:

§ 293.405 Disposition of records.

(a) When the OPF of a non-SES employee is sent to another servicing office in the employing agency, to another agency, or to the National Personnel Records Center, the "losing" servicing office shall include in the OPF all performance ratings of record that are 4 years old or less, including the performance plan on which the most recent rating was based, and the summary rating prepared when the employee changes positions, as prescribed in part 430 of this chapter. Also, the "losing" office will purge from the OPF all performance ratings and performance plans that are more than 4 years old, and other performance-related records, according to agency policy established under § 293.404(a)(2) and in accordance with FPM Supplement 293–31.

* * * * *

PART 351—REDUCTION IN FORCE

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 1302, 3502, 3503.

2. Section 351.402 is amended by adding a new paragraph (d), and paragraphs (a), (b), and (c) are republished for the convenience of the reader. As revised § 351.402 reads as follows:

§ 351.402 Competitive area.

(a) Each agency shall establish competitive areas in which employees compete for retention under this part.

(b) A competitive area may consist of all or part of an agency. The minimum competitive area in the departmental service is a bureau, major command, directorate or other equivalent major subdivision of an agency within the local commuting area. In the field, the minimum competitive area is an activity under separate administration within the local commuting area. A competitive area must be defined solely in terms of an agency's organizational unit(s) and geographical location, and it must include all employees within the competitive area so defined.

(c) When a competitive area will be in effect less than 90 days prior to the effective date of a reduction in force, a description of the competitive area shall be submitted to the OPM for approval in advance of the reduction in force. Descriptions of all competitive areas must be made readily available for review.

(d) Each agency shall establish a separate competitive area for each Inspector General activity established under authority of the Inspector General Act of 1978, Public Law 95–452, as amended, in which only employees of that office shall compete for retention under this part.

3. Section 351.504 is amended by revising paragraph (b), the introductory text to paragraph (c), and the introductory text to paragraph (d) as set out below. The remainder of the section is republished for the convenience of the reader. As revised § 351.504 reads as follows.

§ 351.504 Credit for performance.

(a) Annual performance ratings of record of outstanding (Level 5), exceeds fully successful (Level 4), fully successful (Level 3), minimally successful (Level 2), and unacceptable (Level 1), or equivalent, are those ratings established under part 430 of this chapter.

(b)(1) An employee's entitlement to additional service credit for performance under this subpart shall be based on the employee's three most recent annual performance ratings of record received during the 4-year period prior to the date of issuance of reduction in force notices, except as provided in paragraph (b)(2) of this section.

(2) To provide adequate time to determine employee retention standing, an agency may provide for a cutoff date—a specified number of days prior to the issuance of reduction in force notices—after which no new annual ratings will be put on record and used for purposes of this subpart. When a cutoff date is used, an employee will receive performance credit for the three most recent annual ratings received during the 4-year period prior to the cutoff date.

(3) To be creditable for purposes of this subpart, a rating must have been issued to the employee, with all appropriate reviews and signatures, and must also be on record (e.g., the rating is available for use by the office responsible for establishing retention registers).

(4) The awarding of additional service credit based on performance for purposes of this subpart must be

uniformly and consistently applied, and must be consistent with the agency's performance appraisal system, and other appropriate issuances that implement these policies. Each agency must specify in its performance appraisal system or other appropriate issuance:

(i) The types of annual performance ratings of record that are used for purposes of this subpart;

(ii) The conditions under which a rating is considered to have been received for purposes of determining whether it is within the 4-year period prior to either the date the agency issues reduction in force notices or the agency-established cutoff date for ratings, as appropriate; and

(iii) If the agency elects to use a cutoff date, the number of days prior to the issuance of reduction in force notices after which no new annual ratings will be put on record and used for purposes of this subpart.

(c) Service credit for employees who do not have three actual annual performance ratings of record received during the 4-year period prior to the date of issuance of reduction in force notices, or the 4-year period prior to the agency-established cutoff date for ratings permitted in paragraph (b)(2) of this section, shall be determined as follows:

(1) An employee who has not received an annual performance rating of record shall receive credit for performance on the basis of three assumed ratings of fully successful (Level 3) or equivalent.

(2) An employee who has received at least one but fewer than three previous annual performance ratings of record shall receive credit for performance on the basis of the actual rating(s) received and of one, or two assumed ratings(s) of fully successful (Level 3) or equivalent, whichever is needed to credit the employee with three ratings.

(d) The additional service credit an employee receives for performance under this subpart shall be expressed in additional years of service and shall consist of the mathematical average (rounded in the case of a fraction to the next higher whole number) of the employee's last three (actual and/or assumed) annual performance ratings of record computed on the following basis:

(1) Twenty additional years of service for each performance rating of outstanding (Level 5) or equivalent;

(2) Sixteen additional years of service for each performance rating of exceeds fully successful (Level 4) or equivalent; or

(3) Twelve additional years of service for each performance rating of fully successful (Level 3) or equivalent.

(e) The current annual performance rating of record shall be the last annual rating except that:

(1) An employee who has received an improved rating following an opportunity to demonstrate acceptable performance as provided in part 432 of this chapter shall have the improved rating considered as the current annual performance rating of record; and

(2) An employee's current annual performance rating of record shall be presumed to be fully successful when the employee had been demoted or reassigned under part 432 of this chapter because of unacceptable performance and as of the date of issuance of reduction in force notices has not received a rating for performance in the position to which demoted or reassigned.

(4) Section 351.701 is amended by revising paragraph (a) to read as follows:

§ 351.701 Assignment involving displacement.

(a) *General.* When a group I or II competitive service employee with a current annual performance rating of record of minimally successful (Level 2) or equivalent, or higher, is released from a competitive level, an agency shall offer assignment, rather than furlough or separate, in accordance with paragraphs (b), (c), and (d) of this section to another competitive position which requires no reduction or the least possible reduction in representative rate. The employee must be qualified for the offered position. The offered position shall be in the same competitive area and last at least 3 months. Upon accepting an offer of assignment, or displacing another employee under this part, an employee retains the same status and tenure in the new position. The promotion potential of the offered position is not a consideration in determining an employee's right of assignment.

5. Section 351.703 is revised to read as follows:

§ 351.703 Exception to qualifications.

An agency may assign an employee to a vacant position under § 351.201(b) or § 351.701 of this part without regard to OPM's standards and requirements for the position if:

(a) The employee meets any minimum education requirement for the position; and

(b) The agency determines that the employee has the capacity, adaptability, and special skills needed to satisfactorily perform the duties and responsibilities of the position.

6. Section 351.704 is amended by revising paragraph (a)(1) and adding a new paragraph (b)(4) as set out below. The remainder of the section is republished for the convenience of the reader. As revised § 351.704 reads as follows:

§ 351.704 Rights and prohibitions.

(a)(1) An agency may satisfy an employee's right to assignment under § 351.701 by assignment under § 351.201(b) or § 351.705 to a position having a representative rate equal to that to which he or she would be entitled under § 351.701.

(2) An agency may, at its discretion, choose to offer under this part a vacant other-than-full-time position to a full-time employee or to offer a vacant full-time position to an other-than-full-time employee in lieu of separation by reduction in force.

(b) Section 351.701 does not:

(1) Authorize or permit an agency to assign an employee to a position having a higher representative rate;

(2) Authorize or permit an agency to displace a full-time employee by an other-than-full time employee, or to satisfy an other-than-full-time employee's right to assignment by assigning the employee to a vacant full-time position.

(3) Authorize or permit an agency to displace an other-than-full-time employee by a full-time employee, or to satisfy a full-time employee's right to assignment by assigning the employee to a vacant other-than-full-time position.

(4) Authorize or permit an agency to assign a competing employee to a temporary position (i.e., a position under an appointment not to exceed 1 year), except as an offer of assignment in lieu of separation by reduction in force under this part when the employee has no right to a position under § 351.701 or § 351.704(a)(1) of this part. This option does not preclude an agency from, as an alternative, also using a temporary position to reemploy a competing employee following separation by reduction in force under this part.

7. Section 351.803 is amended by revising paragraph (b) to read as follows:

§ 351.803. Content of notice.

* * * * *

(b) The notice shall state specifically the employee's competitive area, competitive level, subgroup, service date, and annual performance ratings of record received during the last 4 years as provided in § 351.504 of this part.

[FR Doc. 91-29996 Filed 12-16-91; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Parts 842 and 843

RIN: 3206-AE02

Federal Employees Retirement System—Basic Annuity; Death Benefits and Employee Refunds

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is adopting as final its proposed rules under the Federal Employees Retirement System (FERS) that (1) amend portions of the interim regulations governing the so-called "Minimum Retirement Age (MRA) plus 10" and the "early deferred" retirement provisions; (2) make technical corrections and conforming changes to the rules governing service credit deposits and survivor elections; and (3) amend the rules concerning the basic employee death benefit to permit a widow(er) who had elected to receive that benefit in installments to take the present value of the remaining payments in a single payment.

EFFECTIVE DATE: January 16, 1992.

FOR FURTHER INFORMATION CONTACT: Robert M. Rosenblatt, (202) 606-0775, extension 207.

SUPPLEMENTARY INFORMATION: On July 5, 1991, OPM published (56 FR 30701) proposed regulations that made a number of changes under subpart B, C, and F of 5 CFR part 842, and Subpart C of 5 CFR part 843. OPM received no comments on these rules. However, a letter from one agency expressed concern about a sentence in the Supplementary Information that, the agency felt, seemed to introduce a new rule. In fact, the meaning of that sentence (the last sentence beginning on page 30701) had been inadvertently distorted by the misplacement of a word. The sentence should have read as follows:

> If a refund of CSRS deductions has been paid and the individual later becomes subject to FERS, *and* the service is counted under FERS rules, a FERS deposit is required which is computed as if no deductions had been made for the service at issue.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only affect Federal agencies and retirement payments to retired Government employees, spouses, and former spouses.

List of Subjects in 5 CFR Parts 842 and 843

Administrative practice and procedure, Claims, Disability benefits, Firefighters, Government employees, Law enforcement officers, Air traffic controllers, Pensions, Retirement, Survivors.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM is amending 5 CFR part 842 and 5 CFR part 843 as follows:

PART 842—FEDERAL EMPLOYEES RETIREMENT SYSTEM—BASIC ANNUITY

1. The authority citation for part 842 continues to read as follows:

Authority: 5 U.S.C. 8461(g); sections 842.104 and 842.106 also issued under 5 U.S.C. 8461(n); section 842.105 also issued under 5 U.S.C. 3402(c)(1); section 842.106 also issued under section 7202(m)(2) of the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508; sections 842.604 and 842.611 also issued under 5 U.S.C. 8417; section 842.607 also issued under 5 U.S.C. 8416 and 8417; section 842.614 also issued under 5 U.S.C. 8419; section 842.615 also issued under 5 U.S.C. 8418; § 842.703 also issued under sec. 7001(a)(4) of the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508; section 842.707 also issued under section 6001 of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203; section 842.708 also issued under section 4005 of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239 and section 7001 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508; subpart H also issued under 5 U.S.C. 1104.

Subpart B—Eligibility

2. Section 842.204 is amended by revising paragraph (a)(1) and (c)(3), and by adding paragraph (d) to read as follows:

§ 842.204 Immediate voluntary retirement—basic age and service requirements.

(a) * * *

(1) Except as provided in paragraph (d) of this section, after attaining the minimum retirement age and completing 10 years of service; or

* * * * *

(c) * * *

(3) A postponed commencing date must be no later than the second day before the employee's 62nd birthday.

* * * * *

(d)(1) If an employee or Member separates from service after attaining the minimum retirement age and completing 10 years of service, but is reemployed before filing an application for retirement based on that separation, the individual may not elect an annuity commencing date that precedes separation 34from the reemployment service.

(2) In the case of an employee or Member who separates from service after attaining the minimum retirement age and completing 10 years of service, and is reemployed after filing an application for retirement based on that separation, that individual may not elect an annuity commencing date that precedes separation from the reemployment service if he or she is reemployed prior to a postponed commencing date elected under paragraph (c) of this section.

3. § 842.212 is amended by revising paragraph (b)(1) and adding paragraph (c) to read as follows:

§ 842.212 Deferred retirement.

* * * * *

(b)(1) Except as provided in paragraphs (b)(3) and (c) of this section, an employee or Member who has not attained the minimum retirement age, and who, after completing 10 years of service, is separated or transferred to a position in which the individual is no longer covered by FERS, is entitled to a deferred annuity commencing—

(i) The first day of the month following the date on which the individual attains the minimum retirement age or, if later,

(ii) A date the individual designates that follows the date on which the designation is filed.

* * * * *

(c)(1) If an employee or Member separates from service after completing 10 years of service but before attaining the minimum retirement age, and is reemployed before filing an application for retirement based on that separation, that individual may not elect an annuity commencing date that precedes separation from the reemployment service.

(2) In the case of an employee or Member who separates from service after completing 10 years of service but before attaining the minimum retirement age, and is reemployed after filing an application for retirement based on that separation, that individual may not elect an annuity commencing date that precedes separation from the reemployment service if he or she is reemployed prior to a postponed commencing date elected under paragraph (b).

Subpart C—Credit for Service

4. § 842.305 is amended by revising paragraphs (a) and (e)(3) to read as follows:

§ 842.305 Deposits for Civilian Service.

(a) *Eligibility—current and former employees or Members.* An employee or Member subject to FERS and a former employee or Member who is entitled to an annuity may make a deposit for civilian service described under paragraphs (a)(2) and (a)(3) of § 842.304 upon application to OPM in a form prescribed by OPM. A deposit for civilian service cannot be made later than 30 days after the first regular monthly payment as defined in § 842.602.

* * * * *

(e) * * *

(3) Interest is computed from the midpoint of each service period included in the computation. The interest accrues annually on the outstanding portion, and is compounded annually, until the portion is deposited. Interest is not charged after the commencing date of annuity or for a period of separation from the service that began before October 1, 1956.

* * * * *

Subpart F—Survivor Elections

5. Section 842.602 is amended by adding a new definition in alphabetical order to read as follows:

§ 842.602 Definitions.

* * * * *

First regular monthly payment means the first annuity check payable on a recurring basis (other than an estimated payment or an adjustment check) after OPM has initially adjudicated the regular rate of annuity payable under FERS and has paid the annuity accrued since the time of retirement. The "first regular monthly payment" is generally preceded by estimated payments before the claim can be adjudicated and by an adjustment check (including the difference between the estimated rate and the initially adjudicated rate).

* * * * *

6. Section 842.608 is revised to read as follows:

§ 842.608 Changes of election before final adjudication.

An employee or Member may name a new survivor or change his or her election of type of annuity if, not later than 30 days after the date of the first regular monthly payment, the named survivor dies or the employee or Member files with OPM a new written election. All required evidence of spousal consent or justification for waiver of spousal consent, if applicable, must accompany any new written election under this section.

§ 842.609 [Removed]

7. Section 842.609 is removed and reserved.

8. Section 842.610 is amended by revising paragraph (a) to read as follows:

§ 842.610 Changes of election after final adjudication.

(a) Except as provided in § 842.611, § 842.612, or paragraph (b) of this section, an employee or Member may not revoke or change the election or name another survivor later than 30 days after the date of the first regular monthly payment.

* * * * *

PART 843—FEDERAL EMPLOYEES RETIREMENT SYSTEM—DEATH BENEFITS AND EMPLOYEE REFUNDS

9. The authority citation for part 843 continues to read as follows:

Authority: 5 U.S.C. 8461; §§ 843.205, 843.208, and 843.209 also issued under 5 U.S.C. 8424; § 843.309 also issued under 5 U.S.C. 8442; § 843.406 also issued under 5 U.S.C. 8441.

Subpart C—Current and Former Spouse Benefits

10. Section 843.309 is amended by adding paragraph (c) to read as follows:

§ 843.309 Basic Employee Death Benefit.

* * * * *

(c)(1)(i) A current spouse who has elected to receive the basic employee death benefit in 36 installments under paragraph (b)(2) of this section may elect to receive the remaining portion of the basic employee death benefit in one payment.

(ii) The election to receive the remaining portion of the basic employee death benefit in one payment must be in writing and signed by the current spouse.

(iii) The election to receive the remaining portion of the basic employee death benefit in one payment is irrevocable when OPM authorizes the payment.

(2) Upon the death of a current spouse who was receiving the basic employee death benefit in 36 installments under paragraph (b)(2) of this section, the remaining portion of the basic employee death benefit will be paid as one payment to the estate of the current spouse.

(3) As used in this section, "remaining portion of the basic employee death benefit" means the amount of the basic employee death benefit computed under paragraph (a) of this section that has not been paid. The amount is the remaining principal computed based on an amortization schedule with the initial principal equal to the amount computed under paragraph (a) of this section and the interest rate based on the applicable factor under paragraph (b)(2) of this section.

[FR Doc. 91-29997 Filed 12-16-91; 8:45 am]
BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[FV-91-421FR]

Handling of Almonds Grown in California; Change of Date for Satisfying Inedible Disposition Obligations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule changes from July 31 to August 31 each year, the date by which handlers of California almonds must satisfy their inedible disposition obligations. The action was unanimously recommended by the Almond Board of California (Board), the agency responsible for local administration of the Federal marketing order for California almonds. The purpose of this action is to provide handlers with more flexibility in their operations.

EFFECTIVE DATE: January 16, 1992.

FOR FURTHER INFORMATION CONTACT: Sonia N. Jimenez, Marketing Specialist, Marketing Order Administration Branch, room 2525-S, F&V, AMS, USDA, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 475-5992.

SUPPLEMENTARY INFORMATION: This final rule is issued under marketing agreement and Order No. 981 [7 CFR part 981], both as amended, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended [7 U.S.C. 601-674], hereinafter referred to as the "Act."

This final rule has been reviewed by the U.S. Department of Agriculture (Department) under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 105 handlers of California almonds subject to regulation under the marketing order for almonds grown in California during the current season. There are approximately 7,000 producers in the regulated area. Small agricultural producers have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of handlers and producers of California almonds may be classified as small entities.

This final rule will amend § 981.442(a)(5) of the Administrative Rules and Regulations issued pursuant to the order, to allow handlers until August 31 of each year to satisfy their inedible disposition obligations. This action is based on a unanimous recommendation of the Board and upon other available information.

Section 981.42 of the order provides that handlers are required to deliver a quantity of almond kernels equal to their inedible disposition obligation to the Board or Board accepted crushers, feed manufacturers, or feeders. A handler's inedible disposition obligation is the percentage of inedible kernels in lots received by such handler during a crop year, as determined by the Federal-State Inspection Service (inspection agency), less any tolerance in effect for the crop year. Section 981.42 also provides that the Board may establish rules and regulations necessary to the administration of these provisions.

Section 981.442(a)(5) of the regulations provides that each handler's inedible disposition obligation is satisfied when the almond meat content of the material delivered to accepted users equals the inedible disposition obligation, but no later than July 31 succeeding the crop year in which the obligation was incurred. On June 28, 1991, an interim final rule [56 FR 29561] changed the July 31 date to August 31 for handlers' inedible disposition obligations for the 1990–91 crop year only.

At its June 13, 1991, meeting, the Board recommended further amending § 981.442(a)(5), to allow handlers until August 31 to satisfy their inedible disposition obligation for the 1991–92 and subsequent seasons. A proposed rule on this action was published in the **Federal Register** on September 26, 1991 [56 FR 48765]. Comments were received until October 28, 1991. One comment was received favoring the proposed action.

The comment received was from Blue Diamond Growers, Inc. The commenter stated that the tremendous growth in the industry over the last decade has turned the almond business from a seasonal one to a year round sales effort. The approval of this action will provide handlers with more flexibility in their operations. Also, this will provide handlers with sufficient time to process their growers' crops and complete the sorting out of the inedible materials. Further, extending the date until August 31 should not interfere with the processing of new crop almonds, as harvest generally begins in early September.

This action relaxes restrictions on almond handlers and does not impose any additional burden or costs on handlers.

Based on the above, the Administrator of the AMS has determined that the issuance of this final rule will not have significant economic impact on a substantial number of small entities.

After consideration of all relevant material presented, including the information and recommendation submitted by the Board and other available information, it is found that this action as hereinafter set forth will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 981 is amended as follows:

PART 981—ALMONDS GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 981 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

Subpart—Administrative Rules and Regulations

2. The last sentence in paragraph (a)(5) of § 981.442 is revised to read as follows:

Note: This action will appear in the Annual Code of Federal Regulations.

§ 981.442 Quality control.

(a) * * *

(5) * * * Each handler's disposition obligation shall be satisfied when the almond meat content of the material delivered to accepted users equals the disposition obligation, but no later than August 31 succeeding the crop year in which the obligation was incurred.

* * * * *

Dated: December 11, 1991.

Robert C. Keeney,

Deputy Director Fruit and Vegetable Division.

[FR Doc. 91–29989 Filed 12–16–91; 8:45 am]

BILLING CODE 3410–02–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 376

[DoD Directive 5100.81]

Department of Defense Support Activities (DSAs)

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This part establishes Department of Defense Support Activities (DSAs) as an organizational category within the Department. This part defines the term DSA; specifies the criteria which DSAs must satisfy; prescribes policy and assigns responsibilities under which DSAs shall be established, supported, and operate; and includes a list of approved DSAs. The primary mission of a DSA is to perform technical and/or analytical support functions for the Office of the Secretary of Defense (OSD). For appropriate organizational, management, or efficiency reasons, DEAs are located outside the OSD and within another DoD Component. DSAs function under the authority, direction, and control of an OSD Principal Staff Assistant, and receive manpower, operational funding, and other administrative support from the DoD Component in which the DSA is located.

EFFECTIVE DATE: December 5, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. D. Clark, telephone (703) 697–1142.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 376

Organization and functions (Government agencies)

Accordingly, title 32, chapter I, subchapter R, is amended by adding part 376 to read as follows:

PART 376—DEPARTMENT OF DEFENSE SUPPORT ACTIVITIES (DSAs)

Sec.

376.1 Purpose.
376.2 Applicability.
376.3 Definitions.
376.4 Policy.
376.5 Responsibilities.

Appendix A to Part 376—List of Department of Defense Support Activities (DSAs)

Authority: 10 U.S.C. 131.

§ 376.1 Purpose.

Under the authority vested in the Secretary of Defense by Title 10, United States Code, this part:

(a) Establishes DSAs as an organizational category within the Department.

(b) Prescribes policy and assigns responsibilities under which DSAs shall operate.

§ 376.2 Applicability.

This part applies to the Office of the Secretary of Defense (OSD), the Military Departments, the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Unified and Specified Commands, the Inspector General of the Department of Defense, the Defense Agencies, and the DoD Field Activities (hereafter referred to collectively as "the DoD Components").

§ 376.3 Definitions.

(a) *Department of Defense Support Activity (DSA).* An organizational entity of the Department of Defense whose primary mission is to perform technical and/or analytical support functions for the OSD. A DSA must satisfy all of the following criteria:

(1) Function under the direction, authority, and control of an OSD Principal Staff Assistant.

(2) Perform technical and/or analytical support functions in specific areas of interest—as distinct from the normal OSD functions of developing policy, managing resources, and evaluating and overseeing programs.

(3) Have a primary organizational mission to perform assigned functions for a designated OSD Principal Staff Assistant(s)—as distinct from organizations whose primary mission is to provide support for all or several DoD Components.

(4) Be organizationally located outside the OSD and within another DoD Component for appropriate organizational, management, or efficiency reasons.

(5) Receive manpower, operational funding, and other administrative support from the DoD Component in which the DSA is located.

(b) *OSD Principal Staff Assistant(s).* The Under Secretaries of Defense, the Director of Defense Research and Engineering, the Assistant Secretaries of Defense, the General Counsel of the Department of Defense, the Comptroller of the Department of Defense, the Assistants to the Secretary of Defense, and the OSD Directors or equivalents who report directly to the Secretary or Deputy Secretary of Defense.

§ 376.4 Policy.

A DSA shall be established in accordance with this part when it is the most efficient and effective organizational alternative for accomplishing essential technical and/or analytical support functions for an OSD Principal Staff Assistant, and shall be organized and staffed in a manner that permits the effective accomplishment of assigned responsibilities with a minimum number of personnel. To provide a framework for implementing this policy, the Director of Administration and Management shall maintain:

(a) A DoD-wide definition and criteria for DSAs.

(b) An approved list of DSAs.

(c) A procedure for establishing, disestablishing, and modifying the organization of a DSA(s).

(d) A common method of accounting for DSA personnel, and for separately and visibly describing DSA support funding and costs within the DoD budget.

§ 376.5 Responsibilities.

(a) The Director of Administration and Management, Office of the Secretary of Defense, shall:

(1) Be the DoD approval authority, with concurrence by the Assistant Secretary of Defense (Force Management and Personnel) (ASD(FM&P)) and the Comptroller of the Department of Defense (C, DoD), for requests from OSD Principal Staff Assistants to establish or disestablish a DSA(s), or to change the mission and functions of an existing DSA. Approval will be subject to funding and manpower availability, along with other relevant factors.

(2) Be the DoD approval authority for requests from an OSD Principal Staff Assistant to increase the overall funding level for DSA(s) under that official's sponsorship. Increases that would add to the overall funding level of the separate DSA budget line in the O&M Defense Agencies Appropriation are subject to fund availability, and shall be addressed through the normal budget process.

(3) Maintain, monitor, and revise, as necessary, the official list of DSAs in appendix A to this part.

(4) Conduct periodic reviews to evaluate the continuing requirement for existing DSAs, and to ensure that the DoD components are accounting for DSAs in accordance with this part.

(b) The Assistant Secretary of Defense (Force Management and Personnel) shall review DSA manpower authorizations and issue guidance to ensure compliance with manpower levels established by the Secretary of Defense or by law.

(c) The Comptroller of the Department of Defense shall:

(1) Establish a separate DSA budget activity in the O&M Defense Agencies Appropriation.

(2) Review DSA supporting resource data contained in requests from OSD Principal Staff Assistants to establish a DSA(s), and in subsequent DSA budget submissions.

(3) Ensure that all funds required to support a DSA are separately and visibly described and justified in the budget of the DoD Component designated to provide administrative support to that DSA.

(d) The OSD Principal Staff Assistants shall:

(1) Forward requests for establishing or disestablishing a DSA(s), or for modifying the organization of an existing DSA (if changes to currently approved manpower for funding levels are required), to the Director, Administration and Management (DA&M), OSD for approval. Recommendations for establishing a DSA shall include: Assignment of DSA responsibilities, functions, relationships, authorities; identification of funding support and other resources to be allocated; appropriate organizational, management, or efficiency justification for establishing the DSA outside the OSD organizational structure; and designation of the DoD Component that will provide manpower, operational funding, and other administrative support to the DSA.

(2) When approved, establish the DSA in accordance with this part, and ensure that the DSA is efficiently organized and staffed.

(3) Exercise authority, direction, and control over the DSA(s) assigned to their respective offices.

(4) Ensure appropriate internal management controls are established for DSAs assigned to their office, in accordance with DoD Directive 5010.38 [1].

(5) Ensure all personnel assigned to a DSA under their authority are accounted for as OSD Management Headquarters Support personnel, in accordance with DoD Directive 5100.73 [2].

(6) Be the approval authority for reallocations between personnel and non-personnel funds within a single DSA under their authority, and for reprogramming funds between DSAs under their authority, as long as the overall funding level for those DSAs is not exceeded and no other DoD reprogramming restrictions are in effect. Requests for increases that would add to the overall funding level of the DSAs under thier authority shall be referred to the DA&M, OSD for approval, consistent with paragraph (a)(2) of this section.

(7) As required, develop a memorandum of understanding (MOU) with the DoD Component designated to provide administrative support to a DSA(s) assigned to their office. MOUs shall comply with this part and, as a minimum, include supervisory, policymaking, and operating instructions, and establish required administrative controls.

(e) The Heads of the DoD Components designated to provide support to a DSA shall:

(1) Provide manpower and operational funding to the assigned DSA(s).

(2) Provide full administrative support to the assigned DSA(s) in accordance with this part and any implementing MOU that may be completed with the sponsoring OSD Principal Staff Assistant. In the case of the Defense Logistics Agency, administrative support to the assigned DSAs shall be provided on a reimbursable basis; the necessary additional funding to accommodate this requirement will be included in the appropriate DSA budget.

(3) Account for all personnel assigned to a DSA as OSD Management Headquarters Support personnel, maintain DSA manpower strength data by category of personnel (military and civilian), and report the data, under DoD Directive 5100.73, as a separate "OSD DSA" item in the Future Years Defense Program using Defense Planning and Programming Category program element code ending in "98."

(4) Submit a DoD Management Headquarters Exhibit (PB–22) and a Reconciliation of Increases and Decreases Exhibit (OP–5) which specifically identify the assigned DSA(s) to the C, DoD, in accordance with DoD 7110.1–M [3].

(5) Ensure all DSA manpower requirements and budget documentation are appropriately coordinated with and approved by the sponsoring OSD Principal Staff Assistant, prior to submission to cognizant OSD officials.

(6) Ensure all funds required to support the DSA are separately and visibly described and justified in the Component budget.

Appendix A to Part 367—List of Department of Defense Support Activities (DSAs)

[1] Copies may be obtained, at cost, from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

[2] See footnote 1 to § 367.5(d)(4).

[3] Copies may be obtained, by written requests, to the Office of the Assistant Secretary of Defense (Public Affairs), Room 2C757, Pentagon, Washington, DC 20301.

DoD support activity	OSD sponsor (OSD principal staff assistant)	DoD component responsible for administrative support
1. Defense Technology Analysis Office	Director, Defense Research & Engineering (DDR&E)	Defense Logistics Agency (DLA).
2. Intelligence Program Support Group	Assistant Secretary of Defense (Command, Control, Communications & Intelligence).	Defense Intelligence Agency (DIA).
3. Defense Productivity Program Office	ASD (FM&P)	DLA.
4. Defense Manpower Data Center	ASD (FM&P)	DLA.
5. Defense Training & Performance Data Center	ASD(FM&P)	DLA.
6. DoD Civilian Personnel Systems Center	ASD(FM&P)	DLA.
7. Vulnerability & Analysis Branch, Military Studies & Analysis Division, Joint Data Systems Support Center, Defense Information Systems Agency (DISA).	Assistant Secretary of Defense (Program Analysis & Evaluation).	DISA.
8. Defense Installations Support Office	Assistant Secretary of Defense (Production & Logistics) (ASD(P&L)).	DLA.
9. Defense Analysis & Studies Office	ASD(P&L)	DLA.
10. Defense Environment Support Office	ASD(P&L)	DLA.
11. Management Support Center (Includes Administrative Support Office)	ASD(P&L)	DLA.
12. Defense Logistics Support Office	ASD(P&L)	DLA.
13. Defense Procurement Support Office	USD(A)	DLA.
14. Defense Production Resources Support Office	ASD(P&L)	DLA.
15. Defense Systems & Programs Office	ASD(P&L)	DLA.
16. Total Quality Management Support Office	Under Secretary of Defense (Acquisition)	DLA.

Dated: December 10, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-29883 Filed 12-16-91; 8:45 am]

BILLING CODE 3810-01-M

Defense Logistics Agency

32 CFR Part 1285

[Defense Logistics Agency Regulation 5400.14]

Defense Logistics Agency Freedom of Information Act Program

AGENCY: Defense Logistics Agency, DoD.

ACTION: Final rule.

SUMMARY: The Defense Logistics Agency operates its Freedom of Information Act Program in accordance with DoD 5400.7-R (32 CFR part 286) which provides the policies and procedures for the Department of Defense (DoD) and the DoD Components. This final rule establishes procedures for obtaining information from DLA under the provisions of the FOIA, 5 U.S.C. 552, and revises 32 CFR part 1285.

EFFECTIVE DATE: December 17, 1991.

FOR FURTHER INFORMATION CONTACT: Susan Salus, Freedom of Information Act Officer, Administrative Management Branch, Resources Management Division, Defense Logistics Agency, room 5A120, Cameron Station, Alexandria, Virginia 22304-6100. Telephone 703-617-7583.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 1285

Freedom of information.

Gary C. Tucker,

Colonel, USA, Director of Administration.

Accordingly, 32 CFR part 1285 is revised to read as follows:

PART 1285—DEFENSE LOGISTICS AGENCY FREEDOM OF INFORMATION ACT PROGRAM

Sec.

1285.1 Purpose and scope.
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Appendix A to Part 1285—Gaining Access to DLA Records.

Authority: 5 U.S.C. 552.

§ 1285.1 Purpose and scope.

This rule provides policies and procedures for the DLA implementation of DoD 5400.7-R,[1] DoD Freedom of Information Act Program. It applies to HQ DLA and all DLA field activities and takes precedence over all DLA regulations that supplement the FOIA program. A list of mailing addresses for DLA activities is provided at appendix A to this part.

§ 1285.2 Policy.

(a) *General.* The public has a right to information concerning the activities of its Government. DLA policy is to conduct its activities in an open manner and provide the public with a maximum amount of accurate and timely information concerning its activities, consistent always with the legitimate public and private interests of the American people. A DLA record requested by a member of the public who follows rules established herein shall be withheld only when it is exempt from mandatory public disclosure under the FOIA. In order that the public may have timely information concerning DLA activities, records requested through public information channels by news media representatives that would not be withheld if requested under the FOIA should be released upon request. Prompt responses to requests for information from news media representatives should be encouraged to eliminate the need for these requesters to invoke the provisions of the FOIA and thereby assist in providing timely information to the public. Similarly, requests from other members of the public for information should continue to be honored through appropriate means even though the request does not qualify under FOIA requirements.

(b) *Control system.* A request for records that invokes the FOIA shall enter a formal control system designed to ensure compliance with the FOIA. A release determination must be made and the requester informed within the time limits specified in this rule. Any request for DLA records that either explicitly or implicitly cites the FOIA shall be processed under the provisions of this rule, unless otherwise required by paragraph (m) of this section.

(c) *Compliance with the FOIA.* DLA personnel are expected to comply with the FOIA and this rule in both letter and spirit. This strict adherence is necessary to provide uniformity in the implementation of the DLA FOIA program and to create conditions that will promote public trust. To promote a positive attitude among DLA personnel, each DLA Primary Level Field Activity (PLFA) will establish education and training programs described in part 286, subpart H, of this title. Training materials, including supplements, will be coordinated with DLA-XAM prior to publication or issuance.

(d) *Openness with the public.* DLA shall conduct its activities in an open manner consistent with the need for security and adherence to other requirements of law and regulation. Records not exempt from disclosure under the Act shall, upon request, be made readily accessible to the public in accordance with rules promulgated herein, whether or not the Act is invoked.

(e) *Avoidance of procedural obstacles.* DLA activities shall ensure that procedural matters do not unnecessarily impede a requester from obtaining DLA records promptly. DLA activities shall provide assistance to requesters to help them understand and comply with procedures established by this rule and any rules published by the DLA PLFA's.

(f) *Prompt action on requests.* When a member of the public complies with the procedures established in this rule for obtaining DLA records, the request shall receive prompt attention; a reply shall be dispatched within 10 working days unless a delay is authorized. When a DLA activity has a significant number of requests, e.g., 10 or more, the requests shall be processed in order of receipt. However, this does not preclude an activity from completing action on a request which can be easily answered, regardless of its ranking within the order of receipt. A DLA activity may expedite action on a request regardless of its ranking within the order of receipt upon a showing of exceptional need or urgency. Exceptional need or urgency is determined at the discretion of the activity processing the request.

(g) *Public domain.* Nonexempt records released under the authority of this rule are considered to be in the public domain. Such records may also be made available in reading rooms to facilitate public access. Exempt records released pursuant to this rule or other statutory or regulatory authority, however, may be considered to be in the public domain only when their release constitutes a waiver of the FOIA exemption. When the release does not constitute such a waiver, such as when disclosure is made to a properly constituted advisory committee or to a Congressional committee, the released records do not lose their exempt status. Also, while authority may exist to disclose records to individuals in their official capacity, the provisions of this rule apply if the

[1] Copies may be obtained, at cost, from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161-2171.

same individual seeks the records in a private or personal capacity.

(h) *Creating a record.* (1) There is no obligation to create nor compile a record to satisfy an FOIA request. A DLA activity, however, may compile a new record when doing so would result in a more useful response to the requester or be less burdensome to the activity provided the requester does not object. The cost of creating or compiling such a record may not be charged to the requester unless the fee for creating the record is equal to or less than the fee which would be charged for providing the existing record. Fee assessments shall be in accordance with § 1285.6 of this part and part 286, subpart F, of this title.

(2) With respect to electronic data, the issue of whether records are actually created or merely extracted from an existing database is not always readily apparent. Consequently, when responding to FOIA requests for electronic data where creation of a record, programming, or particular format are questionable, DLA activities should apply a standard of reasonableness. In other words, if the capability exists to respond to the request and the effort would be a business-as-usual approach, then the request should be processed. However, the request need not be processed where the capability to respond does not exist without a significant expenditure of resources, thus not being a normal business-as-usual approach.

(i) *Description of the requested record.* (1) Identification of the record desired is the responsibility of the member of the public who requests a record. The requester must provide a description of the desired record that enables DLA to locate the record with a reasonable amount of effort. When a DLA activity receives a request that does not reasonably describe the requested record, it shall notify the requester of the defect. The requester may be asked to provide the type of information outlined in paragraph (i)(2) of this section. Activities are not obligated to act on the request until the requester responds to the specificity letter. When practicable, DLA activities shall offer assistance to the requester in identifying the records sought and in reformulating the request to reduce the burden on the agency in complying with the Act.

(2) The following guidelines are provided to deal with "fishing expedition" requests and are based on the principle of reasonable effort. Descriptive information about a record may be divided into two broad categories.

(i) Category I is file-related and includes information such as type of record (for example, memorandum), title, index citation, subject area, date the record was created, and originator.

(ii) Category II is event-related and includes the circumstances that resulted in the record being created or the date and circumstances surrounding the event the record covers.

(3) Generally, a record is not reasonably described unless the description contains sufficient Category I information to permit the conduct of an organized, nonrandom search based on the activity's filing arrangements and existing retrieval systems, or unless the record contains sufficient Category II information to permit inference of the Category I elements needed to conduct such a search. The decision of the DLA activity concerning reasonableness of description must be based on knowledge of its files. If the description enables DLA activity personnel to locate the record with reasonable effort, the description is adequate.

(4) The following guidelines deal with requests for personal records. Ordinarily, when only personal identifiers are provided in connection with a request for records concerning the requester, then only records retrievable by personal identifiers need be searched. The search for such records may be conducted under Privacy Act procedures contained in DLAR 5400.21.[2] No record may be denied that is releasable under the FOIA.

(j) *Possession and control.* A record must exist and be in the possession and control of DLA at the time of the search to be considered subject to this rule and the FOIA. Mere possession of a record does not presume Agency control. Information created or originated by another activity shall be referred to that activity for release determination and direct response to the requester.

(1) *Referring requests.* A DLA activity having no responsive records to an FOIA request may refer the request to another DLA activity, DoD component, or Federal agency if, after consultation with such activity, component, or agency, the intended recipient confirms that it has the requested record. In cases where the DLA activity receiving the request has reason to believe that the existence or nonexistence or the record may in itself be classified, that activity shall consult the DoD component having cognizance over the record in question before referring the request. If the DoD component that is consulted determines that the existence or nonexistence of the record is in itself classified, the requester shall be so notified by the DLA activity originally receiving the request, and no referral shall take place. Otherwise, the request shall be referred to the other DoD component, and the requester shall be notified of any such referral. Any DLA activity receiving a request that has been misaddressed shall refer the request to the proper address and advise the requester.

(2) *Referring records.* (i) Whenever a record or a portion of a record is, after prior consultation, referred to another DLA activity, DoD component, or to a Government agency outside of the DoD for a release determination and direct response, the requester shall be informed of the referral. Referred records shall only be identified to the extent consistent with security requirements.

(ii) A DLA activity shall refer an FOIA request for a classified record that it holds to another DoD component or agency outside the Department of Defense if the record originated in the other DoD component or outside agency or if the classification is derivative. In this situation, provide the record and a release recommendation on the record with the referral action.

(iii) A DLA activity may refer a request for a record that it originated to another DoD component or agency when the record was created for the use of the other DoD component or agency. The DoD component or agency for which the record was created may have an equally valid interest in withholding the record as the DLA activity that created the record. In such situations, provide the record and a release recommendation on the record with the referral action.

(iv) Within DLA, an activity shall ordinarily refer an FOIA request for a record that it holds but that was originated by another activity or that contains substantial information obtained from another activity to that activity for direct response after coordination and obtaining concurrence from the activity. The requester shall then be notified of such referral. DLA activities shall not, in any case, release or deny such records without prior consultation with the other activity.

(3) *On-loan documents.* A DLA activity shall refer to the agency that provided the record any FOIA request for investigative, intelligence, or any other type of records that are on loan to DLA for a specific purpose if the records are restricted from further release and so marked. However if, for investigative or intelligence purposes, the outside agency desires anonymity, a DLA

[2] Copies may be obtained, at cost, from DASC-PD, Cameron Station, Alexandria, VA 22304-6130.

activity may only respond directly to the requester after coordination with the outside agency.

(4) *General Accounting Office (GAO) documents.* On occasion, the DoD receives FOIA requests for GAO documents containing DoD information. Even though the GAO is outside the executive branch and not subject to the FOIA, all FOIA requests from GAO documents containing DoD information received either from the public or on referral from GAO will be processed under the provisions of the FOIA.

(5) *Agencies not subject to the FOIA.* A DLA activity may refer an FOIA request for any record that originated in an agency outside the DoD or that is based on information obtained from an outside agency to the agency for direct response to the requester after coordination with the outside agency, if that agency is subject to FOIA. Otherwise, the DLA activity must respond to the request.

(6) *Time to respond.* DLA activities that receive referred requests shall answer them in accordance with the time limits established by the FOIA and this rule. Those time limits shall begin to run upon proper receipt of the referral by the PLFA FOIA manager to respond.

(7) *Accumulating fees.* Requesters receiving the first two hours of search and the first 100 pages of duplication without charge (see part 286, subpart F, of this title) are entitled to such only once per request. Consequently, if a DLA activity, after completing its portion of a request, finds it necessary to refer the request to another DLA activity or another DoD component to action their portion of the request, the referring activity shall inform the recipient of the expended amount of search time and duplication cost to date.

(k) *Requests for authentication of records.* FOIA requests for authentication of records shall be authenticated with an appropriate seal, whenever necessary, to fulfill an official Government or other legal function according to DLA Regulation 5105.5.[3] This service, however, is in addition to that required under the FOIA and is not included in the FOIA fee schedule. DLA activities may charge for the service at a rate of $5.20 for each authentication.

(l) *Records management.* FOIA records shall be maintained and disposed of in accordance with DLA Manual 5015.1.[4]

[3] See Footnote 2 to § 1285.2(i)(4).

[4] See Footnote 2 to § 1285.2(i)(4).

(m) *Relationship between the FOIA and the Privacy Act.* Not all requesters are knowledgeable of the appropriate statutory authority to cite when requesting records. In some instances, they may cite neither Act but will imply one or both Acts. For these reasons, the following guidelines are provided to ensure that requesters receive the greatest amount of access rights under both Acts:

(1) Requesters who seek records about themselves contained in a Privacy Act system of records and who cite or imply the Privacy Act, will have their requests processed under the provisions of the Privacy Act, 5 U.S.C. 552a.

(2) Requesters who seek records about themselves which are not contained in a Privacy Act system of records and who cite or imply the Privacy Act, will have their requests processed under the provisions of the FOIA, since they have no access rights under the Privacy Act.

(3) Requesters who seek records about themselves which are contained in a Privacy Act system of records and who cite or imply the FOIA or both Acts will have their requests processed under the time limits of the FOIA and the exemption and fee provisions of the Privacy Act.

(4) Requesters who seek access to Agency records and who cite or imply the Privacy Act, the FOIA, or both will have their requests processed under the FOIA.

(5) Requesters should be advised in final responses why their request was processed under a particular act.

(n) *Reading rooms.* (1) DLA activities may provide a facility or room where the public may inspect and copy or have copied the so-called "(a)(2)" material (see § 1285.3(b) of this part). At those activities where it is impractical to set up a formal reading room, the FOIA manager will arrange for a review of "(a)(2)" material at a suitable time and location. Identifying details that, if revealed, would create a clearly unwarranted invasion of personal privacy may be deleted from "(a)(2)" materials prior to placement in reading rooms. However, in every case, justification for the deletion must be fully explained in writing. The public's right to inspect first and then decide what is to be copied applies only to "(a)(2)" material. Activities may elect to place other documents in their reading room, including so-called "(a)(1)" material (see § 1285.3(a) of this part), as a means to provide public access to such documents and allow the public to first inspect them before copying. When appropriate, the cost of copying may be imposed on the person requesting the material in accordance with § 1285.6 of this part and part 286, subpart F, of this title.

(2) *"(a)(2)" materials index.* Each activity maintaining a reading room shall maintain an index of the "(a)(2)" materials that are issued, adopted, or promulgated after 4 July 1967. No "(a)(2)" materials issued, promulgated, or adopted after 4 July 1967 that are not indexed and either made available or published may be relied upon or used or cited as precedent against any individual unless such individual has actual and timely notice of the contents of such materials. Each index shall be arranged topically or by descriptive words rather than by case name or numbering system so that members of the public can readily locate material. Case name and numbering arrangements, however, may also be included for the convenience of the DLA activity. Such materials issued, promulgated, or adopted before 4 July 1967 need not be indexed but must be made available upon request if not exempted under part 286, subpart C, of this title.

(3) DLA publications and PLFA supplements may, at the discretion of the DLA activity, be regarded as "(a)(2)" material and placed in reading rooms subject to the restrictions in paragraph (o)(2) of this section. Otherwise, requests for publications will be handled according to paragraph (o)(1) of this section.

(o) *Publications of DLA regulations, manuals, handbooks, and uncontrolled forms.* (1) Since most DLA publications are available to the public through the publications distribution sales outlet, the requester may be referred to that outlet.

(2) Requests for DLA publications which are classified, marked "FOR OFFICIAL USE ONLY," or have limited distribution statements will be referred to the issuing activity for release determination and, if appropriate formal denial. Such publications will not be placed in reading rooms. However, where a public reading room also serves as an activity's library, restricted publications may be maintained provided they are appropriately safeguarded and not commingled with other nonsensitive regulations.

(3) For DoD regulations, manuals, directives, handbooks and similar issuances, the FOIA manager may refer the requester to the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161–2171.

(p) *Exemptions.* The types of records described in part 286, subpart C, of this title may be withheld in whole or in part

from disclosure under the FOIA unless otherwise prescribed by law.

(q) *Requests for the examination of DLA records.* Only those materials described as "(a)(2)" (and "(a)(1)" at the discretion of the PLFA head) are subject to the examination clause of the FOIA. Such requests will be submitted directly to the appropriate DLA activity listed in appendix A. FOIA managers will inform requesters of the location and time the requested record may be examined. Requesters may be charged for the cost to reproduce copies subject to the guidelines § 1285.6 of this part and part 286, subpart F, of this title.

(r) *Requests for copies of records.* Individuals seeking copies of DLA records should address their FOIA requests to the FOIA manager of the appropriate activity. Addresses and brief descriptions of functions are included in appendix A to this part.

(s) *Requests from private parties.* The provisions of the FOIA are reserved for persons with private interests as opposed to Federal Governments seeking official information. Requests from private persons will be made in writing and will clearly show all other addressees within the Federal Government to whom the request was also sent. This procedure will reduce processing time requirements and ensure better inter- and intra-agency coordination. DLA activities are under no obligation to establish procedures to receive hand delivered requests. Release for records to individuals under the FOIA is considered public release of information, except as provided for in paragraph (g) of this section and § 286.13(a) of this title.

(t) *Requests from government officials.* Requests from Members of Congress for records on behalf for a Congressional Committee, Subcommittee, or either House sitting as a whole will be processed according to DLA Regulation 5400.12.[5] Requests from officials of foreign governments which do not invoke the FOIA shall be referred to HQ DLA-I or the appropriate foreign disclosure channel for processing and the requester so notified. Requests invoking the FOIA from the following government officials will be considered the same as any other requested and processed according to this rule:

(1) Officials of State or local governments.

(2) Members of Congress seeking records on behalf of their constituents.

(3) Officials of foreign governments.

(u) *Privileged release to U.S. Government officials.* (1) Records determined to be exempt from public disclosure under one or more of FOIA exemptions may be authenticated and released to U.S. Government officials requesting them on behalf of Federal governmental bodies, whether legislative, executive, administrative, or judicial, as follows:

(i) To a Committee or Subcommittee of Congress or to either House sitting as a whole in accordance with DoD Directive 5400.4.[6]

(ii) To the Federal courts, whenever ordered by officers of the court as necessary for the proper administration of justice. However, receipt of a subpoena *duces tecum* does not automatically compel disclosure of DLA records. To qualify for privileged release under this section, the subpoena must be signed by the judge of a court of competent jurisdiction. A subpoena which has been sent through FOIA channels and signed by a litigating attorney, a subpoena service agent, or an official of a state or local court will be treated as any other FOIA request and subject to the exemptions in Part 286, Subpart C, of this title. Consult with Counsel before acting on such subpoenas.

(iii) To other Federal Agencies, both executive and administrative, as determined by the DLA Director or designee.

(2) Disclosure under these privileged release circumstances does not set a precedent for disclosure to the general public under the FOIA.

(3) DLA activities shall inform officials receiving records under the provisions of this paragraph that those records are exempt from public release under the FOIA and are privileged. DLA activities will also advise officials of any special handling instructions. See part 286, subpart D, of this title for marking requirements under privileged release circumstances.

§ 1285.3 Definitions.

The following terms and meanings shall be applicable:

(a) *"(a)(1) material".* Material described in 5 U.S.C. 552(a)(1) consisting of descriptions of central and field organizations and, to the extent that they affect the public, rules of procedures, descriptions of forms available, instruction as to the scope and contents of papers, reports, or examinations, and any amendment, revision, or report of the aforementioned.

(b) *"(a)(2) material".* Material described in 5 U.S.C. 552(a)(2) encompassing:

(1) Final opinions, including concurring and dissenting opinions, and orders made in the adjudication of cases, as defined in 5 U.S.C. 551, that may be cited, used, or relied upon as precedents in future adjudications.

(2) Statements of policy and interpretations that have been adopted by the agency and are not published in the **Federal Register.**

(3) Administrative staff manuals and instructions, or portions thereof, that establish DLA policy or interpretations of policy that affect a member of the public. This provision does not apply to instructions for employees on tactics and techniques to be used in performing their duties or to instructions relating only to the internal management of the DLA activities. Examples of manuals and instructions not normally made available include but are not limited to the following:

(i) Those issued for audit, investigation, and inspection purposes or those that prescribe operational tactics, standards of performance, or criteria for defense, prosecution, or settlement of cases.

(ii) Operations and maintenance manuals and technical information concerning munitions, equipment, systems, and foreign intelligence operations.

(c) *Administrative appeal.* A request made under the FOIA by a member of the general public asking the appellate authority to reverse an initial denial authority's decision to withhold all or part of a requested record, to review a "no record found" determination, to reverse a decision to deny a request for waiver or reduction of fees, or to review a category determination for fee assessment purposes.

(d) *Agency record.* (1) The products of data compilation, such as all books, papers, maps and photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law in connection with the transaction of public business and in DLA's possession and control at the time the FOIA request is made.

(2) The following are not included within the definition of the word "record":

(i) Objects or articles, such as structures, furniture, vehicles and equipment, whatever their historical value or value as evidence.

(ii) Administrative tools by which records are created, stored, and retrieved, if not created or used as sources of information about

[5] See Footnote 2 to § 1285.2(i)(4).

[6] See Footnote 1 to § 1285.1.

organizations, policies, functions, decisions, or procedures of a DLA activity. Normally, computer software, including source code, object code, and listings of source and object codes, regardless of medium, are not agency records. (This does not include the underlying data which is processed and produced by such software and which may in some instances be stored with the software.) Exceptions to this position are outlined in paragraph (d)(3) of this section.

(iii) Anything that is not a tangible or documentary record, such as an individual's memory or oral communication.

(iv) Personal records of an individual not subject to agency creation or retention requirements, created and maintained primarily for the convenience of an agency employee and not distributed to other agency employees for their official use.

(v) Information stored within a computer for which there is no existing computer program for retrieval of the requested information.

(3) In some instances, computer software may have to be treated as an agency record and processed under the FOIA. These situations are rare and shall be treated on a case-by-case basis. Examples of when computer software may have to be treated as an agency record are:

(i) When the data is embedded within the software and cannot be extracted without the software. In this situation, both the data and the software must be reviewed for release or denial under the FOIA.

(ii) Where the software itself reveals information about organizations, policies, functions, decisions, or procedures of a DLA activity, such as computer models used to forecast budget outlays, calculate retirement system costs, or optimization models on travel costs.

(iii) See part 286, subpart C, of this title for guidance on release determinations of computer software.

(4) A record must exist and be in the possession and control of DLA at the time of the request to be considered subject to this rule and the FOIA. There is no obligation to create, compile, or obtain a record to satisfy an FOIA request.

(5) If unaltered publications and processed documents, such as regulations, manuals, maps, charts and related geophysical materials are available to the public through an established distribution system with or without charge, the provisions of 5 U.S.C. 552(a)(3) normally do not apply, and requests for such need not be processed under the FOIA. Normally, documents disclosed to the public by publication in the **Federal Register** also require no processing under the FOIA. In such cases, DLA activities should direct the requester to the appropriate source to obtain the record.

(e) *Appellate authority.* The Director, DLA, or his designee, except for fee waivers and category determinations. The appellate authority for such appeals is the Staff Director, Office of Administration, HQ DLA.

(f) *DLA activity.* An element of DLA authorized to receive and act independently on FOIA requests. A DLA activity has its own FOIA manager, initial denial authority, and office of counsel.

(g) *Electronic data.* Those records and information which are created, stored, and retrievable by electronic means. This does not include computer software, which is the tool by which to create, store, or retrieve electronic data. See paragraphs (d)(2)(ii) and (d)(3) of this section for a discussion of computer software.

(h) *FOIA request.* A written request for records made by any person, including a member of the public (U.S. or foreign citizen), an organization, or a business, but not including a Federal agency or a fugitive from the law, that either explicitly or implicitly invokes the FOIA, DoD 5400.7–R, DLAR 5400.14, this rule, or DLA activity supplementing regulations or instructions.

(i) *Initial denial authority (IDA).* An official who has been granted authority by the Director, DLA, to withhold records requested under the FOIA for one or more of the nine categories of records exempt from mandatory disclosure or to issue a "no record" determination. These include the Directors (or equivalent) of HQ DLA Primary Staff Elements (PSE's) and the Commanders (or equivalent) of PLFA's. For fee waiver and requester category determinations, the initial denial authority is the FOIA manager or head of the FOIA unit.

(j) *Public interest disclosures.* Those disclosures which shed light on DLA performance of its statutory duties and thus inform citizens about what their government is doing. The "public interest", however, is not fostered by disclosure of information about private citizens that is accumulated in various governmental files that reveals little or nothing about an agency's or official's own conduct. The public interest is one of several factors considered in determining if a fee waiver is appropriate (see part 286, subpart F, of this title).

(k) *Releasing official.* Any individual with sufficient knowledge of a requested record or program to allow him or her to determine if harm would come through release. Releasing officials are at all levels and may be selected to review a particular document because of their expertise in the subject area. The level must be high enough to make sure that releases are made according to the policies outlined here. The authority to release records of a routine nature, such as fact sheets or local directories, may be delegated to any individual at the discretion of the denial authority. In doubtful cases, releasing officials may consult with the FOIA staff or servicing counsel prior to release.

§ 1285.4 Responsibilities.

(a) *The Staff Director, Administration, HQ DLA–X:* (1) Has overall responsibility for establishment and implementation of the DLA FOIA program, providing guidance and instructions to PLFA's and PSE's.

(2) Designates a FOIA manager to administer the DLA FOIA program.

(3) Serves as the point of contact for referring members of the public to the proper DLA source for Agency records.

(4) Serves as appellate authority on fee waivers and category determinations.

(5) Serve as initial denial authority for record denials where more than one PSE is involved or where a PSE has made a determination that the requested record cannot be found.

(6) Submits required reports to the Office of the Assistant Secretary of Defense, Public Affairs.

(7) Collects and deposits fees for FOIA services performed at HQ DLA and DASC.

(b) *The General counsel, HQ DLA–G:* (1) Provides legal advice and assistance to HQ DLA PSE's and, where appropriate, PLFA's in determining decisions to withhold records.

(2) Processes appeals to the Director, DLA, of denials to provide records or "no record" determinations.

(3) Coordinates denial actions with Office of the General Counsel, DoD, and the Department of Justice, as appropriate.

(4) Ensures that case files of FOIA appeals are maintained for 6 years after final agency decision.

(c) *The Staff Director, Office of Public Affairs, HQ DLA–B,* serves as a coordinating office for the release of information to the news media where potential for controversy exists.

(d) *The Staff Director, Office of Congressional Affairs, HQ DLA–Y,* serves as a coordinating office on final

responses to FOIA requests from members of the Congress.

(e) *The heads of the DLA principal staff elements (PSE's):* (1) Appoint an individual to serve as FOIA monitor. Letters of appointment will be forwarded to DLA–XAM.

(2) Forward to DLA–XAM any FOIA request received directly from the public so that the request may be administratively controlled.

(3) Ensures that provisions of this regulation are followed in processing requests for records from the public.

(4) Coordinate requests with other HQ DLA staff elements to the extent considered necessary.

(5) Coordinate any proposed denial with the General Counsel.

(6) Serve as initial denial authority.

(7) Ensure that FOIA case files of denials are maintained for 6 years and that full releases are maintained for 2 years.

(8) Make initial determinations to release records or designate individuals to make such determinations.

(f) *The PSE FOIA monitors:* (1) Process and control all FOIA requests received from DLA–XAM.

(2) Make sure established suspenses are met.

(3) Request extensions of time from DLA–XAM when necessary and within the limits of § 1285.5(j) of this part.

(4) Gather cost estimates when requested.

(5) Ensure costs for processing each Freedom of Information Act request are properly recorded.

(6) Coordinate proposed full and partial denials with DLA–XAM prior to signature by the PSE director. Forward a copy of the final response and cost information to DLA–XAM.

(g) *The heads of DLA primary level field activities (PLFA's):* (1) Designate a FOIA manager to administer the DLA FOIA program within the PLFA. Forward the name, address, and telephone number of the manager to DLA–XAM.

(2) Ensure that the provisions of this regulation are followed in processing requests for records from members of the public.

(3) Provide facilities where members of the public may examine and copy the following documents:

(i) DLAH 5805.1 [7], DLA Organization Directory.

(ii) DLAH 5025.1 [8], DLA Index of Publications.

(iii) DLAM 5015.1, Files Maintenance and Disposition.

(iv) Copies of local directories or indexes.

(v) Any other available "(a)(1)" or "(a)(2)" material.

(4) Sign letters of denial and "no record" determinations after coordination with Counsel.

(5) Refer cases of significance to DLA–XAM for review and evaluation when the issues raised are unusual, precedent setting, or otherwise require special guidance.

(6) Establish safeguards to ensure that FOUO material is protected.

(7) Establish procedures to ensure that a record is maintained of all FOIA requests for logistical data (data on magnetic tape extracted from any of the DLA automated data processing (ADP) systems). The record will contain the requester's name and address, the date of the request, what information was requested, and what information was furnished. This record will be kept for five years.

(8) Inform Public Affairs offices in advance when they intend to withhold or partially withhold a record if it appears that the withholding action may be challenged in the media.

(h) *Freedom of Information Act managers at all levels:* (1) Establish procedures to receive, control, process, and screen FOIA requests. To provide for rapid retrieval of information, FOIA managers will maintain a central log of all incoming FOIA requests.

(2) Review requests to determine if they meet the requirements of 5 U.S.C. 552. Determine category of the requester before assigning the request for search. Provide instructions to the searching office on fees and time limits for response.

(3) Consult with requesters, where necessary, to determine requester category and to resolve fee issues.

(4) Establish training and education program for those personnel who may be involved in responding to FOIA requests.

(5) Approve requests for formal extensions of time and notify requesters in writing of the extension.

(6) Grant or deny requests for fee waivers or requester category determinations and provide DLA–XAM with a copy of each such denial.

(7) Establish procedures to ensure that § 1285.5(1) of this part regarding consultation with submitters of information is complied with.

(8) Establish procedures for the collection and deposit of fees for FOIA services.

(9) Ensure that cost data is maintained for each case file.

(10) Establish procedures to ensure that record denials and "no record" determinations are signed by the PLFA initial denial authority and a copy forwarded to DLA–XAM.

(11) Notify DLA–XAM of requesters who have failed to pay fees in a timely manner.

(12) Prepare and submit reports as required.

(13) Consult with public affairs officers (PAO's) to become familiar with subject matter that is considered to be newsworthy and advise PAO's of all requests from news media representatives.

(14) Establish procedures to provide the Congressional Affairs focal point with an information copy of each FOIA request received from a member of the Congress.

(15) Coordinate any proposed supplements or training material with DLA–XAM prior to publication or dissemination.

(16) Establish procedures to ensure that case files of FOIA releases are maintained for two years after cutoff and that denials are maintained for 6 years after cutoff.

(17) Review all proposed full and partial denials prior to signature by the initial denial authority for compliance with these rules.

§ 1285.5 Procedures.

(a) *FOIA channels.* If DLA personnel receive a FOIA request directly from the public that has not been logged in and processed through the FOIA office, they will immediately forward it to the local FOIA manager.

(b) *Central log system.* Each FOIA manager will maintain a central log of FOIA requests received within the activity to ensure compliance with the time limits and accurate cost accounting, fee assessment, and reporting.

(c) *Time limit.* FOIA requests must be responded to within 10 business days after proper receipt, except in unusual circumstances outlined in paragraph (j) of this section. A request is considered properly received on the date the FOIA manager receives it provided the request has been reasonably described and the requester has either agreed to pay assessable fees or has provided sufficient justification for a fee waiver.

(d) *Screening requests.* (1) Before assigning a request for search, the FOIA manager will screen the request for defects in the description, the requester category, and the issue of fees. FOIA managers will notify requesters of any such defects and, wherever possible, offer assistance to help remedy the

[7] See Footnote 2 to § 1285.2(i)(4).

[8] See Footnote 2 to § 1285.2(i)(4).

defects. If the FOIA manager must consult with the requester on any of the following issues, then the request is not considered to be properly received and the 10-day time limit does not begin or resume until the requester has satisfactorily addressed the issue.

(i) *Payments in arrears.* If a requester has failed to pay fees for a previous request, then the FOIA manager need not process the current request until the requester pays the delinquent amount. In such situations, the FOIA manager will notify the requester of the defect and provide an opportunity to forward payment along with any assessable interest. At that time, the FOIA manager may, at his or her discretion, demand that the requester also pay an estimated fee for the current request.

(ii) *Faulty description.* If the request is not reasonably described, the FOIA manager will notify the requester of the defect and advise that a search cannot be initiated without more specific information. In making such determinations, FOIA managers may consult with offices of primary interest to determine the details that are needed to conduct a search. See also paragraph (f)(2) of this section and § 1285.2(i) of this part.

(iii) *Requester category and fees.* The FOIA manager will analyze the request to determine the category of the requester. If the category of the requester is different than that claimed by the requester, the FOIA manager will:

(A) Notify the requester that he or she should provide additional justification to warrant the category claimed and that a search for responsive records will not be initiated until agreement has been attained relative to the category of the requester. Absent further category justification from the requester and within a reasonable period of time (i.e., 30 calendar days), the FOIA manager shall render a final category determination, and notify the requester of such determination, to include normal administrative appeal rights.

(B) Advise the requester that, notwithstanding any appeal, a search for responsive records will not be initiated until the requester indicates a willingness to pay assessable costs appropriate for the category determined by the FOIA manager. Requesters must submit a fee declaration appropriate for the following categories:

(1) Commercial. Requesters must indicate a willingness to pay all search, review, and duplication costs.

(2) Educational or noncommercial scientific institution or news media. Requesters must indicate a willingness to pay duplication charges in excess of 100 pages if more than 100 pages of records are desired.

(3) All others. Requesters must indicate a willingness to pay assessable search and duplication costs if more than two hours of search effort or 100 pages of records are desired.

(iv) *Justification for fee waivers.* If the requester has asked for a fee waiver but failed to provide a justification, FOIA managers will ask requesters to address the fee waiver criteria in part 286, subpart F, of this title before further processing the request. FOIA managers are reminded that with some types of records, a final decision cannot be made on waiver until after the records have been surfaced, reviewed, and the public benefit and previous public availability assessed.

(2) In cases where there is disagreement on the category of the requester or there is lack of justification for fee waiver, the FOIA manager may process the request without further contacting the requester if he or she believes it can be processed within the automatic $15 waiver limit.

(e) *Providing estimates.* In the situations described by paragraphs (d)(1)(iii) and (d)(1)(iv) of this section, DLA activities must be prepared to provide an estimate of assessable fees if desired by the requester. While it is recognized that search situations will vary among DLA activities and that an estimate is often difficult to obtain prior to an actual search, requesters who desire estimates are entitled to such before committing to a willingness to pay. Should actual costs exceed the actual amount of the estimate or the amount agreed to by the requester, the amount in excess of the estimate or the requester's agreed amount shall not be charged without the requester's agreement.

(f) *Internal processing.* (1) Upon making a determination that the request is reasonably described, that the fee issue has been settled, and that the requester does not owe for a prior request, the FOIA manager will assign the request to the appropriate office of primary interest (OPI) for handling and provide instructions on the category of the requester, the fees to be charged or waived, and what actions the OPI is to take.

(2) After reviewing a request, the OPI may determine, based on knowledge of the files and programs, that a request is, in fact, not reasonably described. OPI's will notify FOIA managers of such defects immediately so that further details may be sought from the requester. Any delays on the requester's part in receiving more detailed information will not count toward the 10-day time limit.

(g) *Initial determinations*—(1) *Reasons for not releasing a record.* There are seven reasons for not complying with a request for a record:

(i) The request is transferred to another DLA activity, DOD component, or to another Federal agency.

(ii) The DLA activity determines through knowledge of its files and reasonable search efforts that it neither controls nor otherwise possesses the requested record. Responding officials will advise requesters of the right to appeal such determinations. See paragraph (i)(5) of this section for details on processing "no record" responses.

(iii) A record has not been described with sufficient particularity to enable the DLA activity to locate it by conducting a reasonable search.

(iv) The requester has failed unreasonably to comply with procedural requirements, including payment of fees, imposed by this rule.

(v) The request is withdrawn by the requester.

(vi) The information requested is not a record within the meaning of the FOIA and this rule.

(vii) The record is denied in accordance with procedures set forth in the FOIA and this rule.

(2) *Reasonably segregable portions.* Although portions of some records may be denied, the remaining reasonably segregable portions must be released to the requester when it reasonably can be assumed that a skillful and knowledgeable person could not reconstruct the excised information. When a record is denied in whole, the response advising the requester of that determination will specifically state that it is not reasonable to segregate portions of the record for release.

(h) *Preparing documents for public release*—(1) *Material containing For Official Use Only marks.* When a determination has been made that a FOUO document may be fully released to a requester under any public information program, the FOUO markings will be removed from the requester's copy prior to release. In cases where a person seeks access to his or her own record and the record is marked FOUO to protect that person's personal or proprietary interests, the FOUO marks will be deleted from the requester's copy prior to release, even though the FOUO status has not been terminated. In such cases, the official file copy will retain the FOUO warning. If only portions of a document marked as FOUO are to be released to the

public under the FOIA, then the exempt portions will be taped out, blackened out, whited out, or cut out and a copy reproduced for the requester from the marked up copy. Initial denial authorities will ensure that the deleted portion cannot be read and that the FOUO marks have been lined through prior to release.

(2) *Material containing classification markings.* The procedures in paragraph (h)(1) of this section apply to classified documents with the exception that the classified portions will be cut out rather than blackened, taped, or whited out. The classification markings on the requester's copy will be deleted prior to release.

(i) *Response to requester*—(1) *Time limits.* Initial determinations to release or deny a record normally shall be made and the decision reported to the requester within 10 working days after receipt of the request by the FOIA manager. When a decision is made to release a record, a copy should be made available promptly to the requester once he has complied with procedural requirements.

(2) *Acknowledging date of receipt.* When the time for response becomes an issue, the official responsible for replying shall acknowledge to the requester the date of the receipt of the request.

(3) *Billing.* When fees are being levied, the response to the requester will contain a billing paragraph. Responding officials will advise requesters to make checks or money orders payable to the United States Treasury and forward them to the FOIA manager of the PLFA that incurred the expense. FOIA managers will notify DLA–XAM of names and addresses of requesters who have failed to pay after a second billing has been mailed and 30 days have elapsed without payment.

(4) *Full and partial denials.* (i) When a request for a record is denied in whole or in part on the basis of one or more of the exemptions in part 286, subpart C, of this title the initial denial authority shall inform the requester in writing and shall explain to the requester the basis for the determination in sufficient detail to permit the requester to make a decision concerning appeal. The requester specifically shall be informed of the exemption(s) on which the denial is based. When the initial denial is based in whole or in part on a security classification, the explanation should include a summary of the applicable Executive Order criteria for classification, as well as an explanation, to the extent reasonably feasible, of how those criteria apply to the particular record in question. The requester shall also be advised of the opportunity and procedures for appealing an unfavorable determination to the Director, DLA.

(ii) FOIA managers shall forward a copy of each letter of denial to DLA–XAM, Cameron Station, Alexandria, Virginia 22304–6100. Do not include attachments, the incoming request, or any backup material.

5. *Providing "no record" responses.* (i) If no documents can be located in response to a FOIA request, the initial denial authority will so advise the requester. Requesters will also be advised that, if they consider the response to be adverse, they may file an appeal within 60 calendar days from the date of the response. Requesters are to be advised to address appeals to the local FOIA manager and include the case number and reasons why they believe the DLA activity should have records on the subject matter.

(ii) Before a formal "no record" response is issued, OPI will verify that the requester has adequately described the record. If additional details will aid the search, then the requester will be asked to provide those details. See paragraph (d)(1)(ii) of this section and § 1285.2(i) of this part for procedures for resolving inadequate descriptions.

(iii) In cases where the requested record has been destroyed, the initial denial authority will confirm that the record was retained for the period authorized in DLAM 5015.1 before issuing a formal response. In responding to requesters in these cases, advise the requester that the records were properly destroyed according to Agency rules for record disposition and give the right to appeal as outlined in paragraph (i)(5)(i) of this section. However, do not ask the requester to provide reasons why the activity should have the records.

(iv) Upon receipt of an appeal, the FOIA manager will direct that a second search be conducted using any information supplied by the requester. If the second search produces no documents, the appeal will be forwarded to HQ DLA–G, Cameron Station, Alexandria, Virginia 22304–6100, along with a copy of the case file. The FOIA manager will include the cost information and an explanation of the method of search and the types of offices searched. In cases where the "no record" response was issued because the records have been destroyed, the FOIA manager will verify that the records were destroyed as provided for in DLAM 5015.1 and provide a statement to that effect.

(v) FOIA managers will ensure that a copy of each "no record" response letter is forwarded to DLA–XAM, Cameron Station, Alexandria, Virginia 22304–6100. Do not include attachments, the incoming request, or any backup material.

(6) *Coordination.* OPI's will ensure that the proposed response is fully coordinated with offices having an interest in the request. Proposed responses to FOIA requests from members of the Congress will be coordinated with DLA–Y or the local Congressional Affairs focal point.

(j) *Extensions of time*—(1) *Formal extensions.* In unusual circumstances, when additional time is needed to respond, the FOIA manager will acknowledge the request in writing within the 10-day period, describe the circumstances requiring the delay, and indicate the anticipated date for substantive response that may not exceed 10 additional working days. Such extensions will be approved on a case-by-case basis. In these unusual cases where the statutory time limits cannot be met and no informal extension of time has been agreed to, the inability to process any part of the request within the specified time should be explained to the requester with a request that he agree to await a substantive response by an anticipated date. It should be made clear that any such agreement does not prejudice the right of the requester to appeal the initial decision after it is made. Since the requester still retains the right to treat this delay as a defacto denial with full administrative remedies, such extensions should be issued only when essential. The unusual circumstances that may be cited to justify delay are:

(i) *Location.* The requested record is located in whole or in part at places other than the office processing the request.

(ii) *Volume.* The request requires the collection and evaluation of a substantial number of records.

(iii) *Consultation.* Consulation is required with other DoD components or agencies having substantial interest in the subject matter to determine whether the records requested are exempt from disclosure in whole or in part under provisions of this rule or should be released as a matter of discretion.

(2) *Informal extensions.* Where practical and expedient, the FOIA manager or official designated to respond may negotiate with the requester and arrange for an informal extension. Such extensions may be appropriate in instances where the records have to be ordered from a record repository; where the record has been sent out for commercial printing and is not expected back before the 10-

day time has elapsed; and similar circumstances.

(k) *Misdirected requests.* Misdirected requests shall be forwarded promptly to the FOIA manager of the DLA activity, DoD component, or Federal agency with the responsibility for the records requested. The period allowed for responding to the request misdirected by the requester shall not begin until the request is received by the FOIA manager of the PLFA that controls the records requested.

(l) *Records of contractors and other non-U.S. government sources.* (1) Executive Order 12600 of 23 June 1987 (52 FR 23781) establishes predisclosure notification procedures for confidential commercial information. When a request is received for a record that was obtained from a contractor or other non-U.S. Government source or for a record containing information clearly identified as having been provided by a contractor or other non-U.S. Government source, the source of the record or information (also known as "the submitter" for matters pertaining to proprietary data under 5 U.S.C. 552(b)(4)) (see § 286.13(a)(4) of this title) shall be notified promptly of that request and afforded reasonable time (e.g., 30 calendar days) to present any objections concerning the release, unless it is clear that there can be no valid basis for objection. The following procedures will be followed:

(i) The person designated to respond will provide the source with a copy of the incoming request, a copy of the documents responsive to the request, and a letter of instruction. The notification letter will be addressed to the president of the entity or the entity's counsel and sent by return receipt mail.

(ii) When a substantial issue has been raised, the DLA activity may seek additional information from the source and afford the source and requester reasonable opportunities to present their arguments on the legal and substantive issues involved.

(iii) Any objections to release will be evaluated and the source provided with a copy of the activity's final decision. Where a decision is made to release information claimed to be exempt, the source will be notified that the information will be released on a specified date unless the source seeks a restraining order or takes court action to prevent disclosure. Evaluators are cautioned that any decision to disclose information claimed to be exempt under 5 U.S.C. 552(b)(4) must be made by an official equivalent in rank to the initial denial authority.

(iv) When the source advises it will seek a restraining order or take court action to prevent release of the record or information, the FOIA manager will notify the requester and suspend action on the request until after the outcome of that court action is known. When the requester brings court action to compel disclosure, the FOIA manager shall promptly notify the submitter of this action.

(2) These procedures are required for those FOIA requests for data not deemed clearly exempt from disclosure under exemption (b)(4). If, for example, the record or information was provided with actual or presumptive knowledge of the non-U.S. Government source and established that it would be made available to the public upon request, there is no obligation to notify the source.

(3) These coordination provisions also apply to any non-U.S. Government record in the possession and control of DLA from multi-national organizations, such as North Atlantic Treaty Organization (NATO) and North American Aerospace Defense Command (NORAD), or foreign governments. Coordination with foreign governments under the provisions of this paragraph shall be made through the Department of State.

(m) *File of initial denials.* Copies of all initial denials shall be maintained by each DLA activity in a form suitable for rapid retrieval, periodic statistical compilation, and management evaluation.

(n) *Appeals.*

(1) *General.*

(i) *Appeals to record denials.* Requesters denied access to records under the provisions of part 286, subpart C, of this title may appeal such determinations to the Director, DLA. The appeal should be accompanied by a copy of the letter denying the initial request and contain the basis for disagreement with the initial refusal.

(ii) *Appeals to a "no record" finding.* Requesters have the right to appeal any "no record" finding to the FOIA manager of the activity that issued the finding. The letter of appeal should include the case number and, where appropriate, reasons why the requester believes the activity should have records on the subject matter. Using the information supplied by the requester, the FOIA manager will direct that a second search be conducted. If the second search produces no documents, the appeal will be forwarded to HQ DLA–G, Cameron Station, Alexandria, Virginia 22304–6100, along with a copy of the case file. The FOIA manager will include information on the amount of time spent on the request and provide an explanation of the method of search and the types of offices searched.

(iii) *Appeals to fee waiver denials or requester category decisions.* Requesters may appeal an initial determination regarding placement in a certain fee assessment category or waiver or reduction of fees when disclosure serves the public interest. Requesters will include a basis for disagreement and submit the appeal to the Staff Director, Office of Administration (Attn: DLA–XAM), Cameron Station, Alexandria, Virginia 22304–6100.

(2) *Time limits*—(i) *Time limits to file appeals.* The requester shall be advised to file an appeal so that it reaches the appellate authority no later than 60 calendar days after the date of the initial denial letter. At the conclusion of this period, the case may be considered closed; however, such closure does not preclude the requester from filing litigation. In cases where the requester is provided several incremental determinations for a single request, the time for the appeal shall not begin until the requester receives the last such notification.

(ii) *Time of receipt.* An FOIA appeal is considered received by DLA when it reaches DLA–G or, in the case of fee or requester category appeals, when it reaches DLA–XAM. Misdirected appeals should be referred expeditiously to the appropriate office.

(iii) *Time limits to decide appeals.* Final determinations on appeals normally shall be made within 20 working days after receipt.

(iv) *Delay in responding to an appeal.* (A) If additional time is needed due to the unusual circumstances described in paragraph (j) of this section, the final decision may be delayed for the number of working days (not to exceed 10), that were not used as additional time for responding to the initial request.

(B) If a determination cannot be made and the requester notified within 20 working days, the appellate authority shall acknowledge to the requester, in writing, the date of receipt of the appeal, the circumstances surrounding the delay, and the anticipated date for substantive response. Requesters shall be advised that if the delay exceeds the statutory extension provision or is for reasons other than the unusual circumstances identified in paragraph (j) of this section, they may consider their administrative remedies exhausted. They may, however, without prejudicing their right of judicial remedy, await a substantive response. DLA shall continue to process the case expeditiously, whether or not the

requester seeks a court order for release of the records, but a copy of any response provided subsequent to filing of a complaint shall be forwarded to the Department of Justice.

(C) When the appellate authority or the authority's representative must consult with the requester over an issue not previously settled, such as agreement to pay fees for documents previously denied, then any delays on the requester's part will not count toward the 20-day time limit.

(3) *Response to the requester.*

(i) When an appellate authority makes a determination to release all or a portion of records withheld by an IDA, a copy of the records so released should be forwarded promptly to the requester after compliance with any preliminary procedural requirements, such as payment of fees.

(ii) Final refusal to provide a requested record must be made in writing by the DLA Director or his designee. In the case of fee appeals, final refusal to waive or reduce fees must be made in writing by the Staff Director of Administration. Record denial responses, at a minimum, shall conform to the following:

(A) The basis for the refusal shall be explained to the requester with regard to the applicable statutory exemption or exemptions invoked.

(B) When the final refusal is based in whole or in part on a security classification, the explanation shall include a determination that the record meets the cited criteria and rationale of the governing Executive Order, and that this determination is based on a declassification review, with the explanation of how that review confirmed the continuing validity of the security classification.

(C) The response shall advise the requester that the material being denied does not contain meaningful portions that are reasonably segregable.

(D) The response shall advise the requester of the right to judicial review.

(4) *Consultaton.* (i) Final refusal involving issues not previously resolved or that are known to be inconsistent with rulings of other DoD components ordinarily should not be made without first consulting with the Office of the General Counsel of the Department of Defense.

(ii) Tentative decisions to deny records that raise new or significant legal issues of potential significance to other agencies of the Government shall be provided to the Department of Justice, Attn: Office of Legal Policy, Office of Information and Policy, Washington, DC 20530.

(5) *Records management.* Case files of appeals shall be retained by DLA–G or, in the case of fee or requester category appeals, by DLA–XAM for a period of six years to meet the statute of limitations of claims requirement.

(o) *Special mail services.* DLA activities are authorized to use registered mail, certified mail, certificates of mailing and return receipts. However, their use should be limited to instances where it appears advisable to establish proof of dispatch or receipt of FOIA correspondence.

(p) *Receipt accounts.* The Treasurer of the United States has established Receipt Account 3210 for use in depositing search, review, and duplication fees collected under the FOIA. Upon receipt of payment, the FOIA manager will forward the check or money order to DFAS/CO/PDG, P.O. Box 182317, Columbus, Ohio 43218–2317. FOIA managers will advise DFAS that the check is to be deposited to accounting classification 21R3210.0004. This account will not, however, be used for depositing receipts for technical information released under the FOIA, industrially-funded activities, and non-appropriated funded activities. Instead, payments for these shall be deposited to the appropriate fund.

§ 1285.6 Fees and fee waivers.

The rules and rates published in part 286, subpart F of this title apply to this rule. For purposes of computer search, DLA has established rates of $20 per minute of central processing unit time for mainframe computer use and $20 per hour of wall clock time for personal computer use. These rates represent average operational costs and may be used when the actual computer cost cannot be determined.

§ 1285.7 Reports.

The reporting requirement outlined in this rule is assigned Report Control Symbol DD–PA(A)1365 and will be prepared according to part 286, subpart G, of this title.

Appendix A to Part 1285—Gaining Access to DLA Records

I. General

The Defense Logistics Agency was established pursuant to authority vested in the Secretary of Defense and is an agency of DoD under the direction, authority, and control of the Assistant Secretary of Defense (Production and Logistics) and is subject to DoD policies, directives, and instructions. DLA is made up of a headquarters and 22 Primary Level Field Activities (PLFA's). DLA does not have a central repository for its records. FOIA requests, therefore, should be addressed to the FOIA Office of the DLA activity that has custody of the record desired. In answering inquiries regarding FOIA requests, DLA personnel will assist requesters in determining the correct DLA activity to address their requests. If there is uncertainty as to the ownership of the DLA record desired, the requester may be referred to the FOIA manager of the DLA activity most likely to have the record or to HQ DLA–XAM.

II. Description of DLA's Central and Field Organization

A. HQ Defense Logistics Agency, Cameron Station, Alexandria, Virginia 22304–6100

The headquarters is organized by broad functional area and includes the following offices and directorates:

Office of the Director.
Executive Director, Contracting.
Executive Director, Supply Operations.
Executive Director, Technical and Logistics Services.
Executive Director, Contract Administration.
Executive Director, Quality Assurance.
Executive Director, Program and Technical Support.
Staff Director, Congressional Affairs.
Staff Director, Public Affairs.
Staff Director, Command Security.
Staff Director, Administration.
Staff Director, Civilian Personnel.
Staff Director, Contracting Integrity.
Staff Director, Military Personnel.
Staff Director, Small and Disadvantaged Business Utilization.
Staff Director, Installation Services and Environmental Protection.
Assistant Director, Information Systems and Technology.
Assistant Director, Policy and Plans.
General Counsel.
Comptroller.

B. The PLFA's.

The 22 PLFA's are organized into six supply centers, four depots, six service centers, and six contract districts.

1. *Supply centers.* The six supply centers are responsible for materiel management of assigned commodities and items of supply relating to food, clothing, textiles, medical, chemical, petroleum, industrial, construction, electronics, and general items of supply. The six supply centers are:

a. Defense Construction Supply Center (DCSC). Buys and manages construction materials, automotive, and construction equipment components, and many repair parts used by the Military Services and other Federal agencies. Manages items ranging from common commercial items such as lumber and plumbing accessories to complex repair parts for mechanical, construction, and automotive equipment, and for military aircraft, surface ships, submarines, combat vehicles, and missile systems.

b. Defense Electronics Supply Center (DESC). Responsible for the acquisition, management, and supply of more than one-half million electronic components such as resistors, capacitors, tubes, transformers, microcircuits, and components for various communications and weapons systems.

c. Defense Fuel Supply Center (DFSC). Serves as material manager for bulk

petroleum and coal and is responsible for its worldwide supply, storage, and distribution.

d. Defense Industrial Supply Center (DISC). Buys and manages industrial items such as bearings, ferrous and nonferrous metals, electrical wire, gasket material, and certain mineral ores and precious metals.

e. Defense Personnel Support Center (DPSC). Buys and manages food, clothing, and medical supplies for all the armed services, some Federal agencies and authorized foreign governments.

f. Defense General Supply Center (DGSC). Buys and manages such categories of materials as electrical hardware, materials handling equipment, kitchen and laundry equipment, woodworking and metalworking machines, photographic supplies, and precision measuring instruments.

2. *Depots.* DLA depots are responsible for the receipt, storage, and distribution of DLA-managed materiel. The principal depots are:
Defense Distribution Region West (DDRW)
Defense Distribution Region East (DDRE)
Defense Depot Memphis (DDMT)
Defense Depot Ogden (DDOU)

3. *Service centers.* DLA operates six service centers which provide technical and logistics services. The service centers are:

a. Defense Logistics Services Center (DLSC). Responsible for maintenance of the Federal Supply Catalog System, including the development and dissemination of cataloging and item intelligence data to the Military Departments and other authorized customers.

b. Defense Reutilization and Marketing Service (DRMS). The central clearinghouse for the reutilization, donation, sale, or disposal of DoD-owned excess property, including scrap and waste.

c. Defense Industrial Plant Equipment Center (DIPEC). Manages the reserve of DoD-owned industrial plant equipment. The center repairs, rebuilds, and updates equipment to avoid new procurement costs.

d. DLA Administrative Support Center (DASC). Provides general administrative support to designated DLA activities.

e. Defense National Stockpile Center (DNSC). Maintains the national reserve of strategic materials stored for use in event of war or other national emergency.

f. DLA Systems Automation Center (DSAC). Develops and maintains DLA's automated and computerized systems.

4. *Contract districts.* Six districts, each responsible for contracts covering a multistate or specialized area, administer materiel contracts after they are awarded by the military services, defense agencies, some civil agencies, and certain foreign governments. The districts are:

Defense Contract Management District Northeast (DCMDN).
Defense Contract Management District Mid Atlantic (DCMDM).
Defense Contract Management District North Central (DCMDC).
Defense Contract Management District South (DCMDS).
Defense Contract Management District West (DCMDW).
Defense Contract Management Command International (DCMCI).

III. Requester Requirements

A. Addressing Requests

Address requests to the DLA PLFA most likely to hold the records (see paragraph V of this appendix for mailing addresses of FOIA managers). If the PLFA is undeterminable, address requests to HQ DLA-XAM for proper routing. Requests must be in writing.

B. Description of Records.

Provide a reasonable description of the documents you are seeking. If you have detailed information which would help reduce the search time involved, please include it in your request. If you have a document which references the DLA record you seek, include a copy of that document.

C. Fees and fee waivers.

State your willingness to pay fees above the $15 automatic waiver or provide a justification for waiver of all or part of the costs. Waiver requests must address with specificity each of the fee waiver elements in part 286, subpart F, of this title.

IV. Availability of DLA Publications

Unrestricted DLA regulations, manuals, and handbooks may be purchased from the DLA publications sales outlet. DLA Handbook 5025.1, Defense Logistics Agency Index of Publications, is published quarterly and may be used to help you identify publications of interest to you. Orders for this and other nonrestricted publications may be placed through DASC-PD, Cameron Station, Alexandria, VA 22304-6130. That office will advise you of cost before completing your order.

V. FOIA Mailing Addresses

HQ Defense Logistics Agency, Attn: HQ DLA-XAM, Cameron Station, Alexandria, VA 22304-6100.
Defense Construction Supply Center, Attn: DCSC-WXA, 3990 E. Broad Street, Columbus, OH 43216-5000.
Defense Electronics Supply Center, Attn: DESC-WXA, 1507 Wilmington Pike, Dayton, OH 45444-5252.
Defense Fuel Supply Center, Attn: DFSC-DB, Cameron Station, Alexandria, VA 22304-6160.
Defense General Supply Center, Attn: DGSC-DB, Richmond, VA 23297-5000.
Defense Industrial Supply Center, Attn: DISC-PPR, 700 Robbins Avenue, Philadelphia, PA 19111-5096.
Defense Personnel Support Center, Attn: DPSC-WXA, 2800 South 20th Street, Philadelphia, PA 19101-8419.
Defense Distribution Region East, Attn: DDRE-WX, New Cumberland, PA 17070-5001.
Defense Depot Memphis, Attn: DDMT-WX, 2163 Airways Blvd., Memphis, TN 38114-5000.
Defense Depot Ogden, Attn: DDOU-G, 800 West 12th Street, Ogden, UT 84407-5000.
Defense Distribution Region West, Attn: DDRW-WX, Tracy, California 95376-5000.
Defense National Stockpile Center Attn: DNSC-L, 1745 Jefferson Davis Highway, Crystal Square No. 4, suite 100, Arlington, VA 22202-3402.
Defense Industrial Plant Equipment Center, Attn: DIPEC-LP, 2163 Airways Blvd., Memphis, TN 38114-5051.
Defense Logistics Services Center, Attn: DLSC-WXA, 74 N. Washington Avenue, Battle Creek, MI 49017-3084.
Defense Reutilization and Marketing Service, c/o Defense Logistics Services Center, Attn: CLSC-WXA, 74 N. Washington Avenue, Battle Creek, MI 49017-3084.
DLA Systems Automation Center, Attn: DSAC-E, P.O. Box 1605, Columbus, OH 43216-5002.
DLA Administrative Support Center, Attn: DASC-RA, Cameron Station, Alexandria, VA 22304-6130.
Defense Contract Management District South, Attn: DCMDS-W, 805 Walker Street, Marietta, Georgia 30060-2789.
Defense Contract Management District Northeast, Attn: DCMDN-WX, 495 Summer Street, Boston, MA 02210-2184.
Defense Contract Management District North Central, Attn: DCMDC-WX, O'Hare International Airport, P.O. Box 66926, Chicago, Il 60666-0926.
Defense Contract Management District West, Attn: DCMDW-WXA, 222 N. Sepulveda Blvd., El Segundo, CA 90245-4320.
Defense Contract Management District Mid Atlantic, Attn: DCMDM-RW, 2800 S. 20th Street, Philadelphia, PA 19101-7478.
Defense Contract Management Command International, Attn: DCMCI-MBW, Wright-Patterson AFB, OH 45433-5000.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[AD-FRL-3977-4]

Preparation, Adoption, and Submittal of State Implementation Plans, Method for Measurement of Condensible Particulate Emissions From Stationary Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Method 202 for the measurement of condensible particulate matter (CPM) was proposed in the **Federal Register** on October 12, 1990, at (55 FR 41546). This action promulgates this method. On April 17, 1990 at (55 FR 14246) EPA promulgated two methods for measuring particulate matter (PM) with an aerodynamic diameter of 10 μm or less (PM_{10}). Since CPM emissions form very fine particles in the PM_{10} size range and are considered PM_{10} emissions, the Agency is adding a method for measuring CPM emissions from stationary sources to appendix M in 40 CFR part 51. The purpose of this

rule is to provide the States with a method for measuring CPM.

EFFECTIVE DATE: December 17, 1991.

ADDRESSES: Background Information Document. The Background Information Document for the promulgated test methods may be obtained from Candace Sorrell or Peter Westlin, MD–19, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–1064. Please refer to "Summary of Comments and Responses for Method 202."

Docket. Docket No. A–90–03, containing materials relevant to this rulemaking, is available for public inspection and copying between 8:30 a.m. to 12 Noon and 1:30 to 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, room M1500, 1st Floor, Gallery 1, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Candace Sorrell or Peter Westlin, Emission Measurement Branch (MD–19), Technical Support Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–1064.

SUPPLEMENTARY INFORMATION:

I. The Rulemaking

The EPA is proposing to add a method for measuring CPM emissions to appendix M in 40 CFR part 51 to provide a method that States can use in their State implementation plans.

II. Public Participation

The opportunity to hold a public hearing on November 2, 1990 at 10 a.m. was presented in the proposal notice, but no one desired to make an oral presentation. The public comment period was from October 12, 1990 to December 17, 1990.

III. Significant Comments and Changes to the Proposed Rulemaking

Six comment letters were received from the proposal rulemaking. A detailed discussion of these comments is contained in the background document entitled "Summary of Comments and Responses for Method 202" which is referred to in the ADDRESSES section of this preamble. The major comments raised in these letters and the Agency's responses follow.

One commenter suggests that EPA determine the chemical composition of the material collected in the sampling train to verify that it will form ambient condensibles.

The EPA believes that material will collect in the impingers only by condensation or dissolution. Dissolved gases will evaporate during analysis and will not be measured unless the gases react to form a solid or liquid while they are in solution. The EPA has designed Method 202 to prevent the formation of reaction materials from dissolved gases. The EPA believes that any remaining material collected and measured by Method 202 represents the material that would condense in the ambient air. Additional analysis of chemical composition is not necessary.

Another comment raises the concern that the method may collect some portion of the sulfur dioxide (SO_2) as condensible.

The dissolution of SO_2 in water does not lead immediately to the formation of sulfuric acid (H_2SO_4), but tends to lower the solution pH, which further inhibits sulfate or H_2SO_4 formation. The method includes a purging procedure which effectively removes SO_2 before significant oxidation occurs. No additional revisions are necessary.

The commenter feels that if EPA is allowing Method 202 to be used in conjunction with Method 201 or 201A or another dry catch procedure to determine the total PM_{10} measurement, the combined methods should be tested for precision.

The imprecision associated with combining Method 202 with Method 201 or 201A or any other dry catch procedure is not additive because each train provides a separate measurement. Since the total precision associated with the combined methods cannot be larger than the least precise sampling method, a precision evaluation of a combined sampling system is unnecessary.

A commenter suggests that EPA add specific language to the applicability section of the method stating that Method 202 cannot be used on wet sources. He notes that Method 17 is excluded from use on wet sources, and Methods 201 and 201A are not recommended for wet sources.

The EPA agrees that Method 202 with an in-stack filter is not recommended for wet sources, and such a statement has been added to the applicability. However, a heated Method 5 filter could be used in Method 202 instead of the in-stack filter which would allow application to wet sources.

One commenter requests that EPA clearly state that Method 202 should not be used for assessing compliance with emission limits set on the basis of data derived from a different measurement approach.

The EPA agrees that a violation must be shown, in the first instance, by means of measurements made with the applicable test method. Once such a showing is made, however, section 113(e) of the Clean Air Act allows the Agency to rely on any credible evidence, including evidence other than the applicable test method, to establish the duration of the period of noncompliance for the purposes of assessing a penalty.

A commenter believes that the sample collection efficiency and method precision may be affected by the sampling conditions such as impinger temperature and sampling flow rate and the method should address this possibility.

The EPA agrees that the nature of the material in the sample gas may affect collection efficiency. For example, a field demonstration of Method 202 at an oil-fired boiler resulted in about 75 percent impinger collection efficiency. This collection efficiency can be improved with the addition of a second filter place between the second and third impinger. This option has been included in the method with a discussion of applicability.

The commenter feels the 1-hour nitrogen (N_2) purge is too long. He believes the majority of the SO_2 is removed in the first few minutes. He suggests the method be revised to reduce the purge time in conjunction with maintaining the sample under cold conditions and analyzing it within 48 hours.

The EPA does not agree with reducing the purge time. Laboratory tests have shown that a 1-hour purge time is necessary to ensure the adequate removal of SO_2 from the impinger solution.

Another commenter suggests that the method should be revised to give credit for ammonium sulfate ($(NH_4)_2SO_2$) dihydrte and other condensible particulate matter formed in the gas stream due to ammonia (NH_3) injection used to enhance the efficiency of a control device.

The EPA does not agree. The condensible particulate matter formed in the gas stream due to NH_3 injection is emitted to the atmosphere. The EPA believes that condensible particulate matter emitted from the source should be counted as such even if it is a product of a pollution-control technique.

The commenter suggests that EPA consider an alternative to $MeCl_2$ consistent with the Montreal Protocol.

The EPA investigated the effectiveness of a chloroform-ether extraction during the method development phase. The chloroform-ether was not as effective as the $MeCl_2$ in removing organic materials; however, the chloroform-ether procedure was

found to be acceptable for organic extraction. The method has been revised to allow a chloroform-ether extraction.

The commenter supports the exclusion of ammonium chloride as a condensible; however, he expresses concern about $(NH_4)_2SO_4$ forming in the impingers.

The N_2 purge removes SO_2 before significant oxidation occurs. If NH_3 is present in the flue gas, the $(NH_4)_2SO_4$ formed in the impingers would not be counted as a condensible, although the H_2SO_4, which reacted with NH_3, would be counted as a condensible. Method 202 corrects for the NH_3 by measuring the sulfate using an IC analysis and subtracting out the ammonium ion (NH_4^+) mass.

The commenter agrees that the NH_3 added during the titration should be subtracted from the final weight. However, he does not agree with adding back in the water removed by the acid-base reaction.

Because H_2SO_4 is hygroscopic, the H_2SO_4 mass found in the atmosphere would have the water attached to it. The method has been revised to allow the source to correct for only the NH_4^+ or for both NH_4^+ and water as an option depending on the basis for the regulation.

A. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principle purposes of the docket are to: (1) Allow interested parties to identify and locate documents so that they can effectively participate in the rulemaking process, and (2) serve as the record in case of judicial review except for interagency review materials (Section 307(d)(7)(A)).

B. Office of Management and Budget Review

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a regulatory impact analysis. This rulemaking would not result in any of the adverse economic effects set forth in Section 1 of the Order as grounds for finding a "major rule." It will neither have an annual effect on the economy of $100 million or more, nor will it result in a major increase in costs or prices. There will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This rulemaking was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

C. Regulatory Flexibility Act Compliance

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this attached rule, if promulgated, will not have any economic impact on small entities because no additional costs will be incurred.

This rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

Dated: December 6, 1991.

F. Henry Habicht II,

Acting Administrator.

List of Subjects in 40 CFR Part 51

Administrative practice and procedure,
Air pollution control,
Carbon Monoxide,
Inter-governmental relations,
Lead,
Nitrogen dioxide,
Ozone,
Particulate matter,
Reporting and recordkeeping requirements,
Sulfur Oxides,
Volatile Organic Compounds.

The EPA amends title 40, chapter I, part 51 of the Code of Federal Regulations as follows:

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: Section 110 of the Clean Air Act as amended (42 U.S.C. 7410).

2. **Appendix M,** to part 51 Table of Contents is amended by adding an entry to read as follows:

Method 202—Determination of Condensible Particulate Emissions From Stationary Sources

3. By adding Method 202 to Appendix M to part 51 to read as follows:

Method 202—Determination of Condensible Particulate Emissions From Stationary Sources

1. Applicability and Principle

1.1 Applicability. 1.1.1 This method applies to the determination of condensible particulate matter (CPM) emissions from stationary sources. It is intended to represent condensible matter as material that condenses after passing through a filter and as measured by this method (Note: The filter catch can be analyzed according to the appropriate method).

1.1.2 This method may be used in conjunction with Method 201 or 201A if the probes are glass-lined. Using Method 202 in conjunction with Method 201 or 201A, only the impinger train configuration and analysis is addressed by this method. The sample train operation and front end recovery and analysis shall be conducted according to Method 201 or 201A.

1.1.3 This method may also be modified to measure material that condenses at other temperatures by specifying the filter and probe temperature. A heated Method 5 out-of-stack filter may be used instead of the in-stack filter to determine condensible emissions at wet sources.

1.2 Principle. 1.2.1 The CPM is collected in the impinger portion of a Method 17 (appendix A, 40 CFR part 60) type sampling train. The impinger contents are immediately purged after the run with nitrogen (N_2) to remove dissolved sulfur dioxide (SO_2) gases from the impinger contents. The impinger solution is then extracted with methylene chloride ($MeCl_2$). The organic and aqueous fractions are then taken to dryness and the residues weighed. The total of both fractions represents the CPM.

1.2.2 The potential for low collection efficiency exist at oil-fired boilers. To improve the collection efficiency at these type of sources, an additional filter placed between the second and third impinger is recommended.

2. Precision and Interference

2.1 Precision. The precision based on method development tests at an oil-fired boiler and a catalytic cracker were 11.7 and 4.8 percent, respectively.

2.2 Interference. Ammonia. In sources that use ammonia injection as a control technique for hydrogen chloride (HC1), the ammonia interferes by reacting with HC1 in the gas stream to form ammonium chloride (NH_4C1) which would be measured as CPM. The sample may be analyzed for chloride and the equivalent amount of NH_4C1 can be subtracted from the CPM weight. However, if NH_4C1 is to be counted as CPM, the inorganic fraction should be taken to near dryness (less than 1 ml liquid) in the oven and then allowed to air dry at ambient temperature to prevent any NH_4C1 from vaporizing.

3. Apparatus

3.1 Sampling Train. Same as in Method 17, section 2.1, with the following exceptions noted below (see Figure 202–1). *Note:* Mention of trade names or specific products does not constitute endorsement by EPA.

3.1.1 The probe extension shall be glass-lined or Teflon.

3.1.2 Both the first and second impingers shall be of the Greenburg-Smith design with the standard tip.

3.1.3 All sampling train glassware shall be cleaned prior to the test with soap and tap water, water, and rinsed using tap water, water, acetone, and finally, $MeCl_2$. It is important to completely remove all silicone grease from areas that will be exposed to the $MeCl_2$ during sample recovery.

3.2 Sample Recovery. Same as in Method 17, section 2.2, with the following additions:

3.2.1 N_2 Purge Line. Inert tubing and fittings capable of delivering 0 to 28 liters/min of N_2 gas to the impinger train from a

standard gas cylinder (see Figure 202–2). Standard 0.95 cm (⅜-inch) plastic tubing and compression fittings in conjunction with an adjustable pressure regulator and needle valve may be used.

3.2.2 Rotameter. Capable of measuring gas flow at 20 liters/min.

3.3 Analysis. The following equipment is necessary in addition to that listed in Method 17, section 2.3:

3.3.1 Separatory Funnel. Glass, 1-liter.

3.3.2 Weighing Tins. 350-ml.

3.3.3 Dry Equipment. Hot plate and oven with temperature control.

3.3.4 Pipets. 5-ml.

3.3.5 Ion Chromatograph. Same as in Method 5F, Section 2.1.6.

4. Reagents

Unless otherwise indicated, all reagents must conform to the specifications established by the Committee on Analytical Reagents of the American Chemical Society. Where such specifications are not available, use the best available grade.

4.1 Sampling. Same as in Method 17, section 3.1, with the addition of deionized distilled water to conform to the American Society for Testing and Materials Specification D 1193–74, Type II and the omittance of section 3.1.4.

4.2 Sample Recovery. Same as in Method 17, section 3.2, with the following additions:

4.2.1 N_2 Gas. Zero N_2 gas at delivery pressures high enough to provide a flow of 20 liters/min for 1 hour through the sampling train.

4.2.2 Methylene Chloride, ACS grade. Blanks shall be run prior to use and only methylene chloride with low blank values (0.001 percent) shall be used.

4.2.3 Water. Same as in section 4.1.

4.3 Analysis. Same as in Method 17, section 3.3, with the following additions:

4.3.1 Methylene Chloride. Same as section 4.2.2.

4.3.2 Ammonium Hydroxide. Concentrated (14.8 M) NH_4OH.

4.3.3 Water. Same as in section 4.1.

4.3.4 Phenolphthalein. The pH indicator solution, 0.05 percent in 50 percent alcohol.

5. Procedure

5.1 Sampling. Same as in Method 17, section 4.1, with the following exceptions:

5.1.1 Place 100 ml of water in the first three impingers.

5.1.2 The use of silicone grease in train assembly is not recommended because it is very soluble in $MeCl_2$ which may result in sample contamination. Teflon tape or similar means may be used to provide leak-free connections between glassware.

5.2 Sample Recovery. Same as in Method 17, section 4.2 with the addition of a post-test N_2 purge and specific changes in handling of individual samples as described below.

5.2.1 Post-test N_2 Purge for Sources Emitting SO_2. (Note: This step is recommended, but is optional. With little or no SO_2 is present in the gas stream, i.e., the pH of the impinger solution is greater than 4.5, purging has been found to be unnecessary.) As soon as possible after the post-test leak check, detach the probe and filter from the impinger train. Leave the ice in the impinger box to prevent removal of moisture during the purge. If necessary, add more ice during the purge to maintain the gas temperature below 20 °C. With no flow of gas through the clean purge line and fittings, attach it to the input of the impinger train (see Figure 202–2). To avoid over- or under-pressurizing the impinger array, slowly commence the N_2 gas flow through the line while simultaneously opening the meter box pump valve(s). When using the gas cylinder pressure to push the purge gas through the sample train, adjust the flow rate to 20 liters/min through the rotameter. When pulling the purge gas through the sample train using the meter box vacuum pump, set the orifice pressure differential to $\Delta H_@$ and maintain an overflow rate through the rotameter of less than 2 liters/min. This will guarantee that the N_2 delivery system is operating at greater than ambient pressure and prevents the possibility of passing ambient air (rather than N_2) through the impingers. Continue the purge under these conditions for 1 hour, checking the rotameter and ΔH value(s) periodically. After 1 hour, simultaneously turn off the delivery and pumping systems.

5.2.2 Sample Handling.

5.2.2.1 Container Nos. 1, 2, and 3. If filter catch is to be determined, as detailed in Method 17, section 4.2.

5.2.2.2 Container No. 4 (Impinger Contents). Measure the liquid in the first three impingers to within 1 ml using a clean graduated cylinder or by weighing it to within 0.5 g using a balance. Record the volume or weight of liquid present to be used to calculate the moisture content of the effluent gas. Quantitatively transfer this liquid into a clean sample bottle (glass or plastic); rinse each impinger and the connecting glassware, including probe extension, twice with water, recover the rinse water, and add it to the same sample bottle. Mark the liquid level on the bottle.

5.2.2.3 Container No. 5 ($MeCl_2$ Rinse). Follow the water rinses of each impinger and the connecting glassware, including the probe extension with two rinses of $MeCl_2$; save the rinse products in a clean, glass sample jar. Mark the liquid level on the jar.

5.2.2.4 Container No. 6 (Water Blank). Once during each field test, place 500 ml of water in a separate sample container.

5.2.2.5 Container No. 7 ($MeCl_2$ Blank). Once during each field test, place in a separate glass sample jar a volume of $MeCl_2$ approximately equivalent to the volume used to conduct the $MeCl_2$ rinse of the impingers.

5.3 Analysis. Record the data required on a sheet such as the one shown in Figure 202–3 Handle each sample container as follows:

5.3.1 Container Nos. 1, 2, and 3. If filter catch is analyzed, as detailed in Method 17, section 4.3.

5.3.2 Container Nos. 4 and 5. Note the level of liquid in the containers and confirm on the analytical data sheet whether leakage occurred during transport. If a noticeable amount of leakage has occurred, either void the sample or use methods, subject to the approval of the Administrator, to correct the final results. Measure the liquid in Container No. 4 either volumetrically to ±1 ml or gravimetrically to ±0.5 g. Remove a 5-ml aliquot and set aside for later ion chromatographic (IC) analysis of sulfates. (Note: Do not use this aliquot to determine chlorides since the HCl will be evaporated during the first drying step; Section 8.2 details a procedure for this analysis.)

5.3.2.1 Extraction. Separate the organic fraction of the sample by adding the contents of Container No. 4 ($MeCl_2$) to the contents of Container No. 4 in a 1000-ml separatory funnel. After mixing, allow the aqueous and organic phases to fully separate, and drain off most of the organic/$MeCl_2$ phase. Then add 75 ml of $MeCl_2$ to the funnel, mix well, and drain off the lower organic phase. Repeat with another 75 ml of $MeCl_2$. This extraction should yield about 250 ml of organic extract. Each time, leave a small amount of the organic/$MeCl_2$ phase in the separatory funnel ensuring that no water is collected in the organic phase. Place the organic extract in a tared 350-ml weighing tin.

5.3.2.2 Organic Fraction Weight Determination (Organic Phase from Container Nos. 4 and 5). Evaporate the organic extract at room temperature and pressure in a laboratory hood. Following evaporation, desiccate the organic fraction for 24 hours in a desiccator containing anhydrous calcium sulfate. Weigh to a constant weight and report the results to the nearest 0.1 mg.

5.3.2.3 Inorganic Fraction Weight Determination. (Note: If NH_4Cl is to be counted as CPM, the inorganic fraction should be taken to near dryness (less than 1 ml liquid) in the oven and then allow to air dry at ambient temperature. If multiple acid emissions are suspected, the ammonia titration procedure in section 8.1 may be preferred.) Using a hot plate, or equivalent, evaporate the aqueous phase to approximately 50 ml; then, evaporate to dryness in a 105 °C oven. Redissovle the residue in 100 ml of water. Add five drops of phenolphthalein to this solution; then, add concentrated (14.8 M) NH_4OH until the sample turns pink. Any excess NH_4OH will be evaporated during the drying step. Evaporate the sample to dryness in a 105 °C oven, desiccate the sample for 24 hours, weigh to a constant weight, and record the results to the nearest 0.1 mg. (Note: The addition of NH_4OH is recommended, but is optional when little or no SO_2 is present in the gas stream, i.e., when the pH of the impinger solution is greater than 4.5, the addition of NH_4OH is not necessary.)

5.3.2.4 Analysis of Sulfate by IC to Determine Ammonium Ion (NH_4^+) Retained in the Sample. (Note: If NH_4OH is not added, omit this step.) Determine the amount of sulfate in the aliquot taken from Container No. 4 earlier as described in Method 5F (appendix A, 40 CFR part 60). Based on the IC SO_4^{-2} analysis of the aliquot, calculate the correction factor to subtract the NH_4^+ retained in the sample and to add the combined water removed by the acid-base reaction (see section 7.2).

5.3.3 Analysis of Water and $MeCl_2$ Blanks (Container Nos. 6 and 7). Analyze these sample blanks as described above in sections 5.3.2.3 and 5.3.2.2, respectively.

5.3.4 Analysis of Acetone Blank (Container No. 8). Same as in Method 17, section 4.3.

6. Calibration

Same as in Method 17, section 5, except for the following:

6.1 IC Calibration. Same as Method 5F, section 5.

6.2 Audit Procedure. Concurrently, analyze the audit sample and a set of compliance samples in the same manner to evaluate the technique of the analyst and the standards preparation. The same analyst, analytical reagents, and analytical system shall be used both for compliance samples and the EPA audit sample. If this condition is met, auditing of subsequent compliance analyses for the same enforcement agency within 30 days is not required. An audit sample set may not be used to validate different sets of compliance samples under the jurisdiction of different enforcement agencies, unless prior arrangements are made with both enforcement agencies.

6.3 Audit Samples. Audit Sample Availability. Audit samples will be supplied only to enforcement agencies for compliance tests. The availability of audit samples may be obtained by writing:

Source Test Audit Coordinator (MD–77B), Quality Assurance Division, Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle, Park, NC 27711

or by calling the Source Test Audit Coordinator (STAC) at (919) 541–7834. The request for the audit sample must be made at least 30 days prior to the scheduled compliance sample analysis.

6.4 Audit Results. Calculate the audit sample concentration according to the calculation procedure described in the audit instructions included with the audit sample. Fill in the audit sample concentration and the analyst's name on the audit response form included with the audit instructions. Send one copy to the EPA Regional Office or the appropriate enforcement agency and a second copy to the STAC. The EPA Regional Office or the appropriate enforcement agency will report the results of the audit to the laboratory being audited. Include this response with the results of the compliance samples in relevant reports to the EPA Regional Office or the appropriate enforcement agency.

7. Calculations

Same as in Method 17, section 6, with the following additions:

7.1 Nomenclature. Same as in Method 17, section 6.1 with the following additions.

C_{cpm} = Concentration of the CPM in the stack gas, dry basis, corrected to standard conditions, g/dscm (g/dscf).

C_{SO4} = Concentration of SO_4^{-2} in the sample, mg/ml.

m_b = Sum of the mass of the water and $MeCl_2$ blanks, mg.

m_c = Mass of the NH_4^+ added to sample to form ammonium sulfate, mg.

m_i = Mass of inorganic CPM matter, mg.

m_o = Mass of organic CPM, mg.

m_r = Mass of dried sample from inorganic fraction, mg.

V_b = Volume of aliquot taken for IC analysis, ml.

V_{ic} = Volume of impinger contents sample, ml.

7.2 Correction for NH_4^+ and H_2O. Calculate the correction factor to subtract the NH_4^+ retained in the sample based on the IC SO_4^{-2} and if desired, add the combined water removed by the acid-base reaction.

$$m_c = K\, C_{so2}\, V_{ic} \qquad \text{Eq. 202–1}$$

where:

K = 0.0205, when correcting for NH_4^+ and H_2O.

= 0.1840, when only correcting for NH_4^+.

7.3 Mass of Inorganic CPM.

$$m_i = m_r \frac{V_{ic}}{V_{ic} - V_b} - m_c \qquad \text{Eq. 202–2}$$

7.4 Concentration of CPM.

$$C_{cpm} = \frac{m_o + m_i - m_b}{V m_{std}} \qquad \text{Eq. 202–3}$$

8. Alternative Procedures

8.1 Determination of NH_4^+ Retained in Sample by Titration.

8.1.1 An alternative procedure to determine the amount of NH_4^+ added to the inorganic fraction by titration may be used. After dissolving the inorganic residue in 100 ml of water, titrate the solution with 0.1 N NH_4OH to a pH of 7.0, as indicated by a pH meter. The 0.1 N NH_4OH is made as follows: Add 7 ml of concentrated (14.8 M) NH_4OH to 1 liter of water. Standardize against standardized 0.1 N H_2SO_4 and calculate the exact normality using a procedure parallel to that described in section 5.5 of Method 6 (appendix A, 40 CFR part 60). Alternatively, purchase 0.1 N NH_4OH that has been standardized against a National Institute of Standards and Technology reference material.

8.1.2 Calculate the concentration of SO_4^{-2} in the sample using the following equation.

$$CSO_4 = \frac{48.03\, V_t\, N}{100} \qquad \text{Eq. 202–4}$$

where

N = Normality of the NH_4OH, mg/ml.

V_t = Volume of NH_4OH titrant, ml.

48.03 = mg/meq.

100 = Volume of solution, ml.

8.3.1 Calculate the CPM as described in section 7.

8.2 Analysis of Chlorides by IC. At the conclusion of the final weighing as described in section 5.3.2.3, redissolve the inorganic fraction in 100 ml of water. Analyze an aliquot of the redissolved sample for chlorides by IC using techniques similar to those described in Method 5F for sulfates. Previous drying of the sample should have removed all HCl. Therefore, the remaining chlorides measured by IC can be assumed to be NH_4Cl, and this weight can be subtracted from the weight determined for CPM.

8.3 Air Purge to Remove SO_2 from Impinger Contents. As an alternative to the post-test N_2 purge described in section 5.2.1, the tester may opt to conduct the post-test purge with air at 20 liter/min. Note: The use of an air purge is not as effective as a N_2 purge.

8.4 Chloroform-ether Extraction. As an alternative to the methylene chloride extraction described in section 5.3.2.1, the tester may opt to conduct a chloroform-ether extraction. Note: The Chloroform-ether was not as effective as the $MeCl_2$ in removing the organics, but it was found to be an acceptable organic extractant. Chloroform and diethylether of ACS grade, with low blank values (0.001 percent), shall be used. Analysis of the chloroform and diethylether blanks shall be conducted according to Section 5.3.3 for $MeCl_2$.

8.4.1 Add the contents of Container No. 4 to a 1000-ml separatory funnel. Then add 75 ml of chloroform to the funnel, mix well, and drain off the lower organic phase. Repeat two more times with 75 ml of chloroform. Then perform three extractions with 75 ml of diethylether. This extraction should yield approximately 450 ml of organic extraction. Each time, leave a small amount of the organic/$MeCl_2$ phase in the separatory funnel ensuring that no water is collected in the organic phase.

8.4.2 Add the contents of Container No. 5 to the organic extraction. Place approximately 300 ml of the organic extract in a tared 350-ml weighing tin while storing the remaining organic extract in a sample container. As the organic extract evaporates, add the remaining extract to the weighing tin.

8.4.3 Determine the weight of the organic phase as described in Section 5.3.2.2.

8.5 Improving Collection Efficiency. If low impinger collection efficiency is suspected, the following procedure may be used.

8.5.1 Place an out-of-stock filter as described in Method 8 between the second and third impingers.

8.5.2 Recover and analyze the filter according to Method 17, Section 4.2. Include the filter holder as part of the connecting glassware and handle as described in sections 5.2.2.2 and 5.2.2.3.

8.5.3 Calculate the Concentration of CPM as follows:

$$C_{cpm} = \frac{m_o + m_i + m_f - m_b}{V m_{std}} \qquad \text{Eq. 202–5}$$

where:

m_f = amount of CPM collected on out-of-stack filter, mg.

8.6 Wet Source Testing. When testing at a wet source, use a heated out-of-stack filter as described in Method 5.

9. Bibliography

1. DeWees, W.D., S.C. Steinsberger, G.M. Plummer, L.T. Lay, G.D. McAlister, and R.T.

Shigehara. "Laboratory and Field Evaluation of the EPA Method 5 Impinger Catch for Measuring Condensible Matter from Stationary Sources." Paper presented at the 1989 EPA/AWMA International Symposium on Measurement of Toxic and Related Air Pollutants. Raleigh, North Carolina. May 1–5, 1989.

2. DeWees, W.D. and K.C. Steinsberger. "Method Development and Evaluation of Draft Protocol for Measurement of Condensible Particulate Emissions." Draft Report. November 17, 1989.

3. Texas Air Control Board, Laboratory Division. "Determination of Particulate in Stack Gases Containing Sulfuric Acid and/or Sulfur Dioxide." *Laboratory Methods for Determination of Air Pollutants.* Modified December 3, 1976.

4. Nothstein, Greg. Masters Thesis. University of Washington. Department of Environmental Health. Seattle, Washington.

5. "Particulate Source Test Procedures Adopted by Puget Sound Air Pollution Control Agency Board of Directors." Puget Sound Air Pollution Control Agency, Engineering Division. Seattle, Washington. August 11, 1983.

6. Commonwealth of Pennsylvania, Department of Environmental Resources. Chapter 139, Sampling and Testing (Title 25, Rules and Regulations, Part I, Department of Environmental Resources, Subpart C, Protection of Natural Resources, Article III, Air Resources). January 8, 1960.

7. Wisconsin Department of Natural Resources. *Air Management Operations Handbook, Revision 3.* January 11, 1988.

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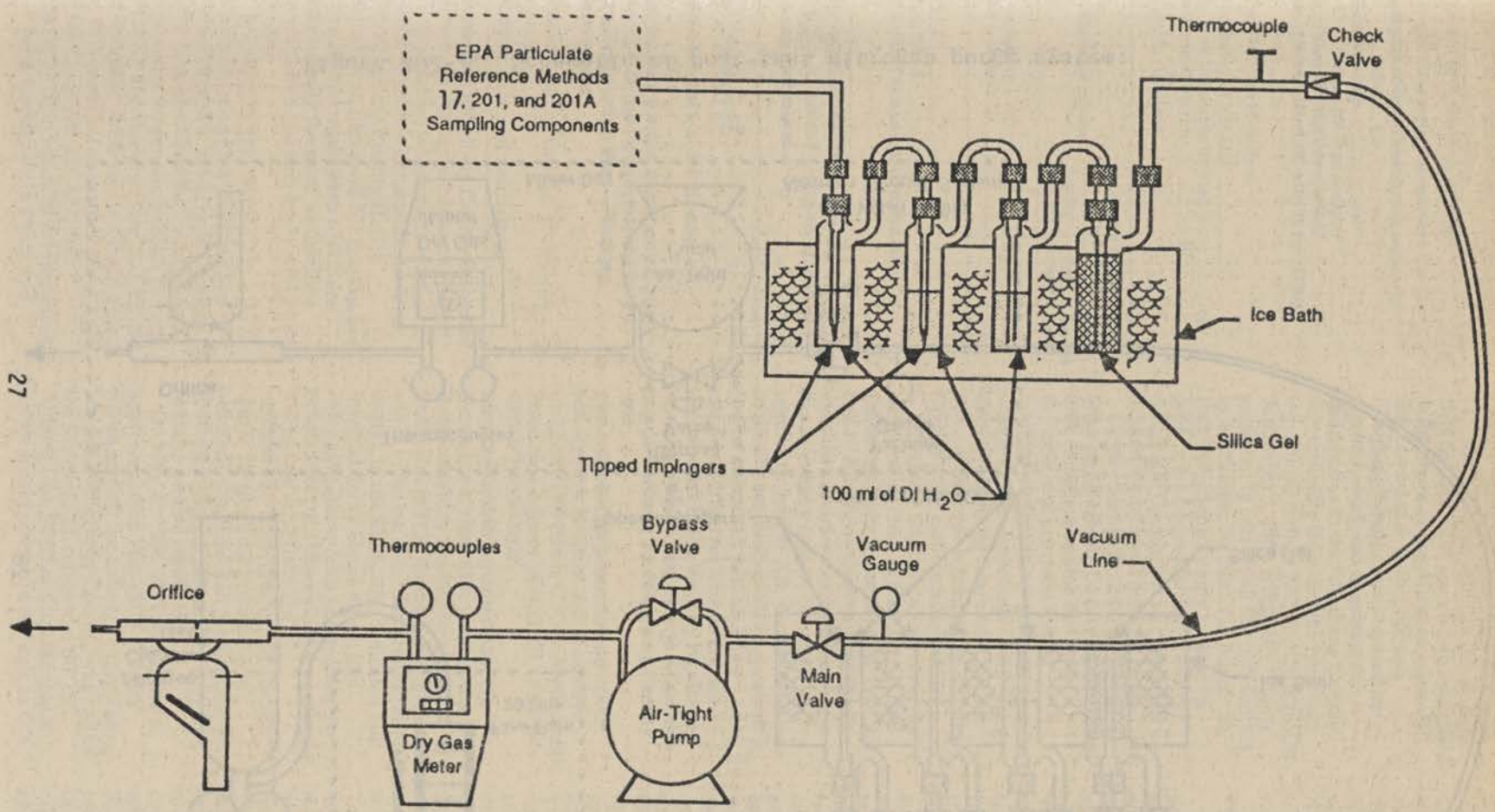


Figure 202-1. Schematic of condensible particulate sampling train.

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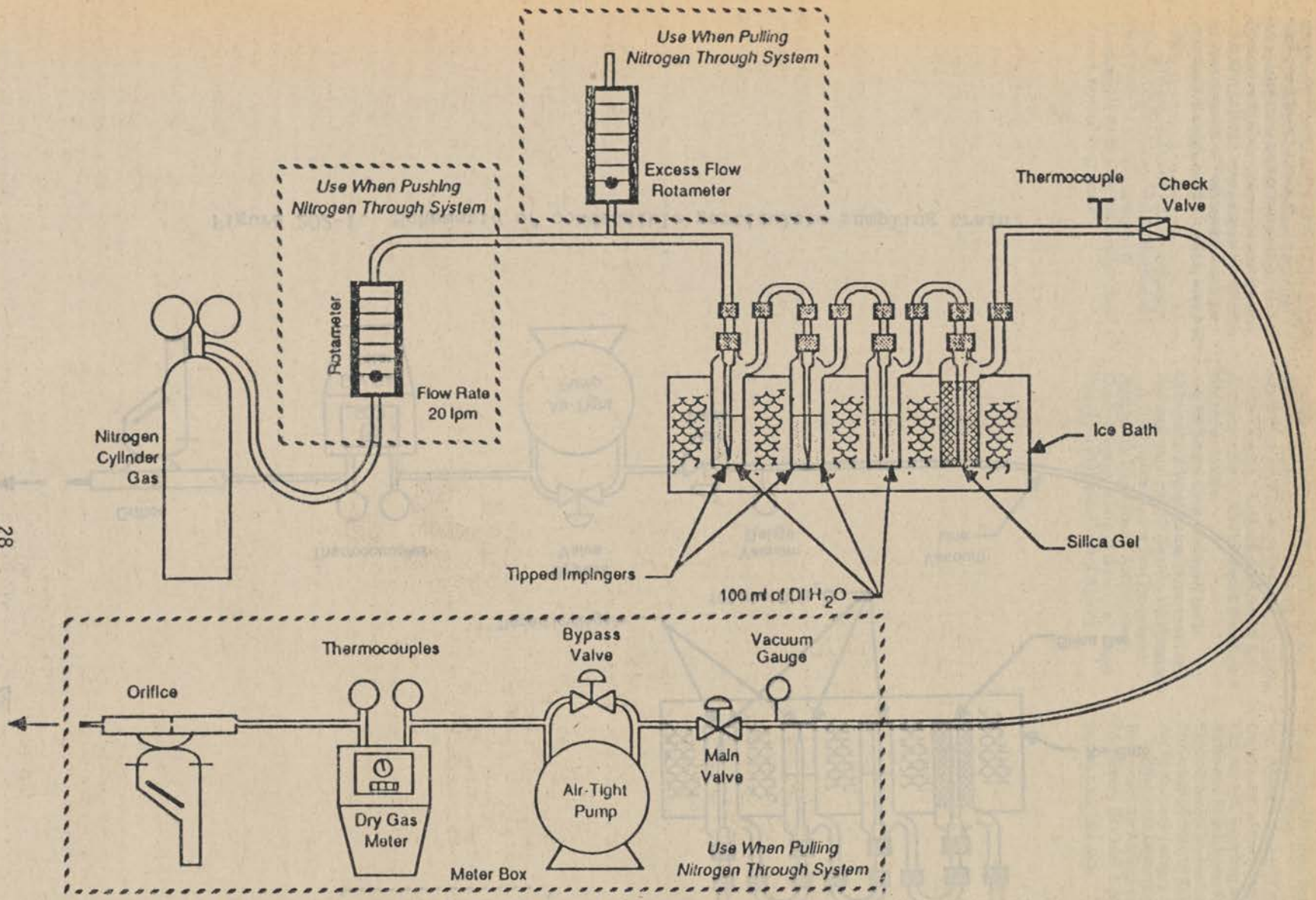


Figure 202-2. Schematic of post-test nitrogen purge system.

Moisture Determination

Volume or weight of liquid in impingers: _____ ml or g

Weight of moisture in silica gel: _____ g

Sample Preparation (Container No. 4)

Amount of liquid lost during transport: _____ ml

Final volume: _____ ml

pH of sample prior to analysis: _____

Addition of NH_4OH required: _____

Sample extracted 2X with 75 ml $MeCl_2$?: _____

For Titration of Sulfate

Normality of NH_2OH: _____ N

Volume of sample titrated: _____ ml

Volume of titrant: _____ ml

Sample Analysis

Container number	Weight of condensible particulate, mg		
	Final weight	Tare weight	Weight gain
4 (Inorganic)			
4 & 5 (Organic)			

Total: _____

Less Blank: _____

Weight of Consensible Particulate: _____

Figure 202–3. Analytical data sheet.

[FR Doc. 91–29957 Filed 12–16–91; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 52

[PA–14–1–5363; A–1–FRL–4083–6]

Deficiency for the Allegheny County Portion of the Pennsylvania State Implementation Plan—Banking Provisions

AGENCY: Environmental Protection Agency.

ACTION: Notice of deficiency.

SUMMARY: Allegheny County is located in western Pennsylvania and is one of seven counties which make up the Pittsburgh ozone nonattainment area. The Allegheny County Health Department, Bureau of Air Quality, has promulgated regulations which are substantially the same as the State regulations but which apply solely to the County.

In a May 26, 1988 State Implementation Plan (SIP) call and in a Federal Register notice on September 21, 1989, EPA identified the Pennsylvania regulations for generic bubbles (title 25, § 129.53) and banking (title 25, § 127.67) as deficient. A SIP call is a finding made by EPA pursuant to section 110(a)(2)(H) of the Clean Air Act, 42 U.S.C. 7410(a)(2)(H) in which EPA identifies a SIP to be inadequate to attain and maintain the National Ambient Air Quality Standard (NAAQS). In a June 14, 1988 follow-up letter to the May 26, 1988 SIP call, EPA specifically identified deficiencies in the Allegheny County SIP. In response to this SIP call, Allegheny County was required to submit a workplan to correct all deficiencies in the Allegheny County SIP, including those for the banking regulations (article XX, Section 808). On September 1, 1988, Allegheny County proposed to correct all SIP deficiencies by September 30, 1989. On August 26, 1991, Allegheny County deleted its generic bubble regulation. However, Allegheny County has not corrected or deleted its deficient banking regulations.

On September 28, 1990, EPA sent a letter to Allegheny County to verify that EPA considers section 808 to be deficient and provided formal notification that this regulation must be changed. The corrections to Allegheny County's banking regulation, section 808, are overdue according to Allegheny County's SIP call commitment.

Therefore, this notice reiterates the deficiencies cited in the June 14, 1988 follow-up letter to the May 26, 1988 SIP call to Allegheny County, specifically identifies deficiencies with respect to the Allegheny County banking regulation (article XX, section 808), and explicitly establishes a 60 day schedule for the submittal, to EPA, of an approvable SIP revision to correct deficiencies in the banking regulations or a draft which proposes to delete this regulation from the Allegheny County SIP.

FOR FURTHER INFORMATION CONTACT: Ms. Cynthia H. Stahl, Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, (215) 597–9337, FTS 597–9337.

SUPPLEMENTARY INFORMATION: On December 4, 1986, EPA published the final Emissions Trading Policy Statement (ETPS) on the banking and use of emission reduction credits (51 FR 43814). In the ETPS, EPA indicated that it would notify States which had deficient generic rules and require the States to correct those rules according to a schedule established in the notification. The ETPS further stated that if the State did not meet the schedule established in the notification, EPA could issue a SIP call with respect to those generic regulations.

On May 26, 1988, EPA issued State Implementation Plan (SIP) calls for States around the nation. Pennsylvania, including Allegheny County, was one of the States which received a SIP call. Although the ETPS anticipated that a notice would precede a SIP call, in this particular case, EPA has already issued a SIP call to Allegheny County because air quality data indicated that the County continued to exceed the ozone standard for the years 1985–87. EPA stated in that SIP call that all deficient VOC regulations must be corrected within one year. Therefore, no further schedule will be established in this Notice for the correction of deficiencies in the Allegheny County banking regulation.

Emission Offsets (Section 808)

The Allegheny County regulations pertaining to the banking of emission credits are located in article XX, section 808 which also imposes criteria for the calculation of emission offsets. The specific subsections in § 808 which relate to banking are B., C., D., E., and G. The Allegheny County banking regulation, like the Pennsylvania banking regulation, does not meet the December 4, 1986 ETPS because, under the Allegheny County regulation, banked emissions are not required to be surplus, enforceable, permanent, and quantifiable. The banking regulation must meet all the requirements specified in that ETPS including such requirements as specifying how emission credits are to be calculated and specifying all the relevant data needed to perform this calculation. Recordkeeping provisions need to be required and clearly stated and a formal system of recording emission credit/debit transactions must be established. Clear records of ownership, available for public inspection must be kept and updated. Provisions must be added to make emission credit deposits state enforceable at the time of deposit and to make emission credit withdrawals both state and federally enforceable at the time of use. As stated in the December 4, 1986 ETPS, emission credits obtained from a bank must meet the requirements of the applicable program(s) for which their use is intended (Whether bubbling to meet Reasonably Available Control Technology (RACT) source regulations or offsetting emissions for prevention of significant deterioration (PSD) or new source review (NSR) purposes) at the time the emission credits are to be used. The State (and the County) must allow for possible adjustments to the banked emission credits for air quality management purposes by stating the conditions under which banked emission credits can be altered or eliminated. The existence of banked emission credits cannot interfere with the State's (or County's) ability to obtain additional emission reductions to attain or maintain ambient air quality

standards. All external offsets must be federally enforceable. External offsets are those emission credit transactions which involve two or more sources of different ownership/control.

Schedules

EPA's SIP call required that Allegheny County submit a workplan by August 15, 1988 indicating the schedule for completing, among other activities, correction of deficiencies including those listed for the generic bubble regulations in Allegheny County. The schedule was not to exceed one year from the date of the workplan submittal. On September 1, 1988, Allegheny County submitted a workplan with a schedule to submit a final draft to correct all SIP deficiencies by September 30, 1989 and to adopt those changes on a schedule dependent on Pennsylvania's adoption of similar changes. The correction of section 808 deficiencies, while implied in the May 26, 1988 SIP call, was not specifically included. However, the SIP call letter stated that while every attempt had been made to identify all deficiencies, the State (or County) was requested to affirm the list of deficiencies by comparing its SIP with the guidance provided. Therefore, Allegheny County should correct the deficiencies identified in section 808 by submitting an approvable SIP revision to EPA by January 17, 1992.

On April 3, 1990, EPA informed Allegheny County that its banking regulations are substantially identical to Pennsylvania's regulations and that its regulations pertaining to bubbles and banking are deficient in the same respect. On September 28, 1990, Allegheny County was formally notified that EPA could begin the process of rescinding approval of, among other provisions, the generic bubble and banking provisions in the Allegheny County SIP if an approvable SIP revision was not submitted. The consequence of rescinding approval of the Allegheny County banking regulation will be to remove Allegheny County's authority to approve banking transactions without prior EPA approval.

Conclusion

Through the May 26, 1988 SIP call, Allegheny County was formally notified that its generic bubble regulations (section 506) and banking regulations (section 808) are deficient. EPA has previously brought to Allegheny County's attention the deficiencies in the banking regulations. Although EPA believes that the May 26, 1988 SIP call provided Allegheny County with formal notification that the banking regulations are deficient, this notice provides further notification of the specific deficiencies in section 808 banking provisions. Nothing in this notice should be construed as implicitly or explicitly making any determination regarding the nonattainment new source review portion of the Allegheny County SIP.

Action

The purpose of this notice is to reiterate the County's previous obligation to correct the banking regulations (or delete them), and to notify Allegheny County that it must submit an approvable SIP revision to EPA by February 18, 1992. Failure to submit an approvable SIP revision could result in an EPA action to rescind federal approval of the banking regulations in Allegheny County.

Under 5 U.S.C. 605(b), the Regional Administrator certifies that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

This Agency action is consistent with the provisions of the 1990 amendments enacted on November 15, 1990. The Agency has determined that this action conforms with those requirements irrespective of the fact that the deficiencies identified in the Allegheny County generic bubble and banking regulations were first identified prior to the 1990 Clean Air Act Amendments.

This action, pertaining to a notice of deficiency for the Allegheny County banking regulation, has been classified as a Table 3 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and Recordkeeping requirements.

Authority: 42 U.S.C. 7401–7642.

Dated: December 6, 1991.

Edwin B. Erickson,

Regional Administrator.

[FR Doc. 91–30098 Filed 12–16–91; 8:45 am]

BILLING CODE 6560–50–M

[OPTS–42118; FRL 3945–8]

40 CFR Part 799

Testing Consent Order For Sodium Cyanide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This document announces that EPA has signed an enforceable testing Consent Order with E.I. du Pont de Nemours and Company (DuPont), FMC Corporation (FMC), Degussa Corporation (Degussa), ICI Americas Incorporated (ICI), and Cyanco Company (Cyanco), hereinafter referred to as "the Companies." The Companies have agreed to perform certain chemical fate and terrestrial effects tests on sodium cyanide (NaCN; CAS No. 143–33–9). This sodium cyanide (NaCN) Consent Order is added to the list of testing consent orders in 40 CFR 799.5000 for which export notification requirements of 40 CFR part 707 apply. This rule constitutes EPA's response to the Interagency Testing Committee's (ITC) recommendation that EPA consider chemical fate and terrestrial effects tests on sodium cyanide.

EFFECTIVE DATE: December 17, 1991.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS–799), Office of Toxic Substances, rm E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Under procedures described in 40 CFR part 790, the Companies have entered into a testing Consent Order with EPA, and have agreed to perform certain chemical fate and terrestrial effects tests for NaCN, (CAS No. 143–33–9). This rule amends 40 CFR 799.5000 by adding NaCN to the list of chemical substances and mixtures subject to testing Consent Orders.

I. Recommendation

In its Twenty-sixth Report to EPA, published in the Federal Register of June 5, 1990 (55 FR 23050), the ITC recommended with intent-to-designate NaCN for environmental effects testing. The rationale for the original recommendation with intent-to-designate appeared in the ITC's Twenty-sixth Report. In its Twenty-seventh Report to EPA published in the Federal Register of March 6, 1991 (56 FR 9534), NaCN was designated as a candidate for rulemaking under TSCA and the testing recommendations were changed because discussions with the Department of Interior (DOI), EPA, and industry identified additional testing data gaps. The Twenty-seventh Report designated certain chemical fate and terrestrial effects tests for NaCN. Specifically, the ITC recommended soil sorption testing as well as testing for

toxicity to migratory birds, plant uptake and translocation.

II. Testing Consent Order Negotiations

In accordance with 40 CFR 790.28, EPA issued a **Federal Register** notice on June 5, 1990 (55 FR 23050), announcing a public meeting and EPA's intent to develop a testing Consent Order or a TSCA section 4 Test Rule for NaCN. EPA requested persons wishing to be designated as "interested parties," or to monitor testing negotiations on NaCN, to contact EPA by July 5, 1990. DuPont, FMC, and Degussa identified themselves as interested parties. On June 20, 1990, EPA convened a public meeting attended by representatives of the interested parties and DOI's Fish and Wildlife Service (FWS) to discuss NaCN testing. DuPont, FMC, and Degussa announced their interest in pursuing testing of NaCN through a testing Consent Order, if a consensus could be reached on the testing necessary to address the concerns raised by DOI. DOI's concerns were detailed in a letter to the ITC (Ref. 1). DOI recommended that the ITC consider further testing of NaCN based upon potential adverse effects to wildlife when NaCN is used commercially to recover precious metals from mine tailings.

During the next year, EPA met with representatives of DOI/FWS to develop a suitable testing program for NaCN. DuPont, FMC, and Degussa were sent a draft testing Consent Order outlining the program, and invited to comment. In addition to submitting written comments on the document, DuPont, FMC, and Degussa requested an opportunity to meet with EPA. EPA convened a meeting on July 9, 1991, with DuPont, FMC, and Degussa at which the parties agreed on data deficiencies and the testing necessary to adequately address these deficiencies. In addition to DuPont, FMC, and Degussa, representatives of ICI and Cyanco expressed interest on behalf of their companies to participate in a testing Consent Order. On November 29, 1991, DuPont, FMC, Degussa, Cyanco, and ICI signed a testing Consent Order for NaCN. The Companies agreed to perform certain chemical fate and terrestrial effects tests by specified dates according to test standards included in this Order.

III. Production and Use

NaCN is a white, crystalline, water soluble compound (Ref. 2). NaCN in the presence of oxygen has the ability to solubilize free gold and silver (and other metals) in a process known as cyanidation. Because of the low cost of NaCN, its use in precious metal leaching processes has become widespread (Ref. 3). DuPont, a domestic manufacturer of cyanide (CN), in 1989 reported a 51 percent increase in CN consumption in North America--from 142 million pounds in 1988 to 215 million pounds in 1989. EPA estimated domestic production of NaCN was approximately 180 million pounds in 1989, and that domestic capacity to produce CN compounds (e.g., NaCN) was likely to double in 1990 (Ref. 4). Goldmining operations consume approximately 80 percent of CN production. Additionally, CN compounds are an important ingredient in processes for electroplating, case hardening of steel, metal cleaning, metals leaching, and ore floatation (Ref. 3).

IV. Testing Program

DOI/FWS will use the data generated by these tests in conjunction with its responsibilities under the Migratory Bird Treaty Act and the National Environmental Policy Act. EPA will use the data to determine the chemical fate of NaCN and potential environmental risks associated with the manufacture, processing, use, and disposal of NaCN and other sources of CN. EPA's Office of Solid Waste (OSW) has expressed interest in using the data to support risk-based or technology-based standards for CN.

A. Chemical Fate

During its use to extract gold and silver from mine tailings, cyanide-containing waters are discharged to impoundments (Ref. 5). Goldmining operations have been shown to yield CN concentrations of 25 to 300 parts per million (ppm) in the water of mill tailings impoundments. Higher concentrations, 500 to 2,000 ppm, occur where the leach process is used. The fresh water impoundments vary from shallow depressions of about 50 feet across to more than 100 acres and depths of 15 feet (Ref. 1). The chemical fate study will allow EPA to assess concerns for groundwater protection at active and abandoned mining sites. The Companies have agreed to develop the chemical fate data as outlined in the table below.

B. Ecological Effects Information

Cyanides are "priority pollutants" under the Clean Water Act. Numerous tests are available that demonstrate the acute toxicity of free cyanide to aquatic organisms. Free cyanide is present in water from the dissolution of such cyanide compounds as sodium cyanide, potassium cyanide, and hydrogen cyanide.

The LC_{50} values for 9 freshwater fish species range from 52 to 350 micrograms per liter; the most sensitive species tested is *Salvelinus fontinalis*. The LC_{50} values for 6 invertebrate species range from 83 to 2,490 micrograms per liter, with the most sensitive species tested being *Daphnia pulex*. The LC_{50} values for 3 marine fish species (*Menidia menidia, Cyprinodon variegatus,* and *Pseudopieronectes americanus*) are 59, 300, and 372 micrograms per liter, respectively. Amphipods are the least sensitive of the marine invertebrates tested (LC_{50} = 1,220 micrograms per liter), and mysids and copepods the most sensitive (LC_{50} values = 30 and 113 micrograms per liter, respectively). In addition, the 96-hour LC_{50} value for the green alga *Scenedesmus quadricauda* is 160 micrograms per liter (Ref. 6).

The letter from DOI nominating NaCN to the ITC contained the following information (Ref. 1):

> Cyanide in water of heap leach and mill tailings ponds associated with precious metal mining has been implicated in substantial wildlife mortality in the western U.S. during the 1980's. As a result of voluntary reporting by 47 mining operations in the State of Nevada, more than 6,000 carcasses of at least 80 species of birds, 17 species of mammals, and a variety of amphibians have been retrieved from these impoundments. Birds, especially aquatic migrants, represented over 90 percent of the total mortalities. Although these mine ponds are not usually associated with prime wildlife habitat, they are frequently located along critical avian migration routes and provide resting sites for opportunistic migrants.

DOI/FWS is concerned about the toxicity of cyanide to migratory birds that alight on ponds containing cyanide contaminated water. Furthermore, there are concerns for the potential plant uptake and potential dietary uptake of CN through the plant; especially once mine reclamation has commenced. The Companies have agreed to develop the terrestrial effects data as outlined in the following table:

TABLE—TESTING REQUIRED FOR SODIUM CYANIDE

Test	Test methods	Start date[1]	Final report date[2]
Chemical Fate Test:			
Sediment and soil adsorption isotherm[3]	40 CFR 796.2750	6	18
Terrestrial Effects Tests:			
Avian dietary toxicity test[4]	WI Protocol	6	18
Mallard reproduction test[5]	WI Protocol	12	30
Plant uptake and translocation test[6]	40 CFR 797.2850	6	24
Plant uptake and translocation test[7]	40 CFR 797.2850	30	48

[1] Number of months after the effective date of the Consent Order.
[2] Number of after the effective date of the Consent Order. Interim (6- month) progress reports shall be submitted to EPA for all tests having final reports dates greater than 9 months, starting 6 months after the start date.
[3] NaCN in water at pH 10.5.
[4] Wildlife International LTD. Protocols 112/090691/MLC/CHP29 (Mallard) and 112/090691/QLC/CHP29 (Bobwhite) are appended to the testing Consent Orde for sodium cyanide.
[5] Wildlife International LTD. Protocol 112/090591/MR/CHP29 is appended to the testing Consent Order for sodium cyanide.
[6] Tier 1: NaCN in water at pH 10.5; at least 2 vegetative species in 1 soil type (sand).
[7] Tier 2: (based on the results of Tier 1): NaCN in water at pH 10.5; 3 vegetative species in 3 soil types (oxidative, sulfitic, and carbonaceous).

C. Test Substance

The test substance, NaCN (CAS No. 143–33–9), shall be as pure a technical grade as can be reasonably attained, but shall be at least 98.0 percent pure.

V. Export Notification

The issuance of the testing Consent Order subjects any persons who export or intend to export the chemical substance, NaCN (CAS No. 143–33–9), of any purity, to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed at 40 CFR part 707. Chemicals subject to testing Consent Orders are listed at 40 CFR 799.5000. This listing serves as a notification to persons who export or intend to export the chemical substance which is the subject of this testing Consent Order that 40 CFR part 707 applies.

VI. Rulemaking Record

A. Supporting Documentation

EPA has established a record for this Consent Order under TSCA section 4, docket number OPTS–42118, which is available for inspection Monday through Friday, excluding legal holidays, in Rm. NE–G004, 401 M St., SW., Washington, DC., 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. This record includes basic information considered by EPA in developing this policy. This record includes the following information:

(1) Testing consent order for NaCN and associated testing protocols.

(2) **Federal Register** notices pertaining to this notice and consent order consisting of:

(a) Notice soliciting interested parties for developing a consent order for sodium cyanide (26th Report of the ITC, June 5, 1990; 55 FR 23050).

(b) 27th Report of the ITC (March 6, 1991; 56 FR 9534).

(3) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone summaries.

(c) Meeting summaries.

(4) Reports - published and unpublished factual materials.

B. References

(1) Buffington, J.D. Letter from John D. Buffington, Regional Director for Research and Development, Fish and Wildlife Service, U.S. Department of Interior to John D. Walker, Acting Executive Secretary, Interagency Testing Committee (ITC), nominating sodium cyanide for consideration by the ITC, (April 17, 1990).

(2) Windholz, M., Budavari, S., Bhumetta, R.F., and Otterbain, E.S., eds., The Merck Index. 10th edition. Rahway, New Jersey. Merck Co., Inc., p. 1233 (1983).

(3) Stanton, M.D., Colbert, T.A., and Trenholm, R.B. The National Park Service Environmental Handbook for Cyanide Leaching Projects. U.S. Department of Interior, Washington, DC (1986).

(4) USEPA. Environmental Protection Agency. Public Focus Meeting for Sodium Cyanide. Office of Toxic Substances, U.S. Environmental Protection Agency (1990).

(5) Fiskel, J., Cooper, C., Eschenroeder, A., Goyer, M., and Perwak, J., "Exposure and risk assessment for cyanide." EPA/440/4–85/008. (NITS P85–220572). Cambridge, MA. Arthur D. Little, Inc. (1981).

(6) USEPA. Environmental Protection Agency. Ambient Water Quality Criteria for Cyanide. Washington, DC., Office of Water Regulation and Standards, U.S. Environmental Protection Agency (1985).

VII. Other Regulatory Requirements

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this Consent Order under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to be 40 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the OMB, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, and Testing.

Dated: November 29, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by adding sodium cyanide to the table in CAS Number order, to read as follows:

§ 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.

* * * * *

CAS Number	Substance or mixture name	Testing	FR citation
*	*	*	*
143-33-9	Sodium Cyanide	Chemical fate Terrestrial effcts	[56 FR December 17, 1991] [56 FR December 17, 1991]
*	*	*	*

* * * * *

[FR Doc. 91-30085 Filed 12-16-91; 8:45 am]
BILLING CODE 6560-50-F

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101-38

[FPMR Temp. Reg. G-48, Supp. 4]

Federal Motor Vehicles Expenditure Control

AGENCY: Federal Supply Service, GSA.
ACTION: Temporary regulation.

SUMMARY: The Office of Management and Budget established the end of fiscal year 1990 as the completion date for studies required by title XV, subtitle C—Federal Motor Vehicle Expenditure Control, Public Law 99-272, Consolidated Omnibus Budget Reconciliation Act of 1985. FPMR Temporary Regulation G-48, dated August 6, 1986, implemented the provisions of this law. This supplement extends the expiration date of FPMR Temp. Reg. G-48 and supplements 1 and 2 thereto to June 30, 1992.

DATES: Effective date: July 1, 1991. Expiration date: June 30, 1992.

FOR FURTHER INFORMATION CONTACT: Karen Hampel, Fleet Management Division (703-557-8276).

SUPPLEMENTARY INFORMATION: The General Services Administration (GSA) has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for and consequences of this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

List of Subjects in 41 CFR Part 101-38

Government property management, motor vehicles.

The authority citation for part 101-38 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486 (c).

In 41 CFR chapter 101, the following supplement to FPMR Temp. Reg. G-48 is added to the appendix at the end of Subchapter G to read as follows:

Federal Property Management Regulations; Temporary Regulation G-48, Supplement 4

November 5, 1991.

To: Heads of Federal agencies.

Subject: Federal motor vehicle expenditure control.

1. *Purpose.* This supplement extends the expiration date of FPMR Temporary Regulation G-48.

2. *Effective date.* This supplement is effective on July 1, 1991.

3. *Expiration date.* This supplement expires June 30, 1992, unless sooner superseded or canceled.

4. *Background.* FPMR Temporary Regulation G-48, dated August 6, 1986, implemented the provisions of title XV, subtitle C—Federal Motor Vehicle Expenditure Control, Public Law 99-272, Consolidated Omnibus Budget Reconciliation Act of 1985. The law and the regulation require that an agency which operates 300 or more motor vehicles to take several actions regarding their motor vehicle operations and activities. The Office of Management and Budget (OMB) is still monitoring agencies implementation of the cost comparison study process. To allow time for analysis and review of agency efforts and to determine what changes are needed to codify a permanent regulation, it is necessary to extend the expiration dates of FPMR Temp. Reg. G-48 and supplements 1 and 2 thereto to June 20, 1992.

5. *Explanation of changes.* The expiration dates in paragraph 3 of FPMR Temp. Reg. G-48 and supplements 1 and 2 of FPMR Temp. Reg. G-48 are extended to June 30, 1992.

Richard G. Austin,
Administrator of General Services.

[FR Doc. 91-29926 Filed 12-16-91; 8:45 am]
BILLING CODE 6820-24-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 63

[CC Docket No. 87-266; FCC 91-334]

Facilities for the Provision of Video Programming by a Telephone Common Carrier in its Telephone Service Area

AGENCY: Federal Communications Commission [FCC].
ACTION: Final rule; Interpretive rulings.

SUMMARY: The Commission issued interpretive rulings concluding that the telephone/cable cross ownership ban of the Cable Act applies only to local exchange carriers and that neither a local exchange carrier nor its customer-programmer need obtain a local cable television franchise to offer video dialtone.

EFFECTIVE DATE: January 16, 1992.

FOR FURTHER INFORMATION CONTACT: Donna Lampert, Common Carrier Bureau, (202) 632-6363 or Greg Lipscomb, Common Carrier Bureau, (202) 634-1800.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The proposals contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980, as amended, 44 U.S.C. 3501-3520, and found to impose no new or modified form, information collection and/or recordkeeping, labeling, disclosure or record retention requirements; and will not increase burden hours imposed on the public. Implementation of any new or modified requirement will be subject to approval by the Office of

Management and Budget as prescribed by that Act.

Background

Common Carrier Docket 87–266: Telephone Company/Cable Television Cross Ownership Rules, §§ 63.54–63.58, Notice of Inquiry, 2 FCC Rcd 5092 (1987) (52 FR 34818 (9/15/87)); Telephone Company/Cable Television Cross Ownership Rules, §§ 63.54–63.58, Further Notice of Inquiry and Notice of Proposed Rulemaking, 3 FCC Rcd 5849 (1988) (53 FR 38042 (9/29/88)).

Summary of First Report and Order

This is a summary of the Commission's First Report and Order relating to Common Carrier Docket 87–266: Telephone Company/Cable Television Cross Ownership Rules, §§ 63.54–63.58, Adopted: October 24, 1991 and Released: November 22, 1991. The full texts of Commission decisions are available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC 20554. The complete text of this First Report and Order may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1114 21st Street, NW., Washington, DC 20036.

In the First Report and Order, the Commission issued an interpretive ruling concluding that the telephone/cable cross ownership ban of the Cable Act does not apply to interexchange carriers and should be interpreted only to apply to local exchange carriers that own or control facilities that provide local exchange service. The Commission also issued an interpretive ruling concluding that neither a local exchange carrier nor its customer-programmer need obtain a local cable television franchise to offer video dialtone.

Ordering Clauses

It is further ordered That, pursuant to sections 1, 4, 214 and 303(r) of the Communications Act, as amended, and sections 613 and 621 of the Cable Communications Policy Act of 1984, 47 U.S.C. 151, 154, 214, 303(r), 533 and 541, the first report and order is adopted.

List of Subjects in 47 CFR Part 63

Cable television, Communications common carriers, Telephone, Video dialtone.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91–30046 Filed 12–16–91; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF ENERGY

48 CFR Part 970

Acquisition Regulation

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) today adopts a final rule which amends the Department of Energy Acquisition Regulation (DEAR) to require management and operating (M&O) contractors to have, and maintain, systems of management and quality controls in order to discourage waste, fraud and abuse. The amendments set forth in this final rule provide guidance and a standardized contract clause to be used in DOE solicitations for, and awards of, M&O contracts. The intended effect of this rule is to enhance the effectiveness of such systems, thereby increasing the likelihood that instances of waste, fraud or abuse are identified and eliminated, and components, products and services provided the DOE meet specifications. This final rule is issued subsequent to a Notice of Proposed Rulemaking (NOPR) published in the **Federal Register** (56 FR 42588) on August 28, 1991.

DATES: *Effective date:* January 16, 1992.

FOR FURTHER INFORMATION CONTACT:

James J. Cavanagh, Business & Financial Policy Division (PR–122), Office of Procurement, Assistance and Program Management, Department of Energy, Washington, DC 20585, (202) 586–8173.

Mary Ann Masterson, Office of the Assistant General Counsel for Procurement and Finance (GC–34), Department of Energy, Washington, DC 20585, (202) 586–1900.

SUPPLEMENTARY INFORMATION:

I. Background
- A. Discussion
- B. Section-By-Section Analysis

II. Procedural Requirements
- A. Review Under Executive Order 12291
- B. Review Under Regulatory Flexibility Act
- C. Review Under Paperwork Reduction Act
- D. Review Under National Environmental Policy Act
- E. Review Under Executive Order 12612

III. Public Comments

I. Background

A. Discussion

As a result of an internal management assessment, DOE has determined that, while all of DOE's M&O contractors have established some form of management and quality controls, greater DOE emphasis on, and oversight of, such systems can enhance the effectiveness of the contractor's systems of controls. The enhanced effectiveness of those controls will increase the likelihood that instances of waste, fraud, or abuse are identified and eliminated, and components, products and services provided DOE meet specification. Internal Departmental guidance assigns appropriate Departmental elements the responsibility for monitoring, ensuring and considering the integrity and efficiency of the M&O contractor operations under their cognizance. While this oversight is presently being performed, there is no explicit DEAR clause requirement for establishment of such controls. DOE does not necessarily envision the mandatory creation of a separate oversight system; rather, the effective coordination and integration of the components of existing systems may suffice. DOE is amending the DEAR to implement appropriate DOE policies, procedures and requirements for systems of controls by DOE's M&O contractors.

B. Section-By-Section Analysis

Part 970

The amendment set forth in the final rule amends subpart 970 to add a new subpart 970.0901 to provide policy guidance concerning DOE's requirements regarding systems of management controls. DOE requires, among other things, that such systems cover both programmatic and administrative functions; that they provide reasonable assurance that Government resources are safeguarded against theft, fraud, waste, mismanagement, loss and abuse; that they promote efficient and effective operations; that they provide for quality assurance controls, standards and assessment techniques; and that they be documented and satisfactory to DOE. The subpart also requires a Management Controls clause to be placed in an M&O contract awarded pursuant to Federal Acquisition Regulation 17.6 and DEAR 917.6.

A new subsection, 970.5204-20, is added which provides the text of the Management Controls clause which, when included in a contract, will implement DOE's requirements regarding systems of management and quality controls to be used as required by 970.0901.

II. Procedural Requirements

A. Review Under Executive Order 12291

This Executive Order, entitled "Federal Regulation," requires that certain regulations be reviewed by the Office of Management and Budget (OMB), prior to their promulgation. The Director, OMB, by memorandum dated

December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. The exemption applies to this rule.

B. Review Under the Regulatory Flexibility Act

This final rule was reviewed under the Regulatory Flexibility Act of 1980, Public law 96–354, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this rule will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Act

No new information collection or recordkeeping requirements are imposed by this rulemaking. Accordingly, no OMB clearance is required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*).

D. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this rule would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. *et seq.* (1976)), or the Council on Environmental Quality regulations (40 CFR parts 1500–1508) and DOE's guidelines (10 CFR part 1021), and, therefore, does not require an environmental impact statement or an environmental assessment pursuant to NEPA.

E. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41285 (October 30, 1987), requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of government. If there are sufficient substantial direct effects, then the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action.

Today's final rule will revise certain policy and procedural requirements. However, DOE has determined that none of the revisions will have a substantial direct effect on the institutional interests or traditional functions of States.

III. Public Comments

Interested persons were invited to participate by submitting data, views, or arguments with respect to the proposed DEAR amendments set forth in a NOPR published in the **Federal Register** (56 FR 42588) on August 28, 1991. Based upon that August 28, 1991, publication date, the public comment period closed on September 27, 1991. During that period, DOE received four comments from interested parties. Those comments, and DOE's response thereto, are set forth below.

Comment: A commenter questioned the need for such a rule given the myriad of requirements for controls systems found in other laws and regulations.

DOE Response: As stated in the preamble to the NOPR, DOE believes that greater emphasis on, and oversight of, such systems are warranted and, therefore, that explicit DEAR regulatory coverage is appropriate.

Comment: Another commenter questioned the need for an explicit rule given that there are numerous separate provisions designed to eliminate waste, fraud, and abuse.

DOE Response: DOE believes that this explicit requirement is needed to focus greater attention on the need to coordinate and integrate these many requirements into a more efficient and effective overall system of controls.

Comment: A commenter found the proposed provisions to be overly broad and lacking specificity as to the appropriate standards.

DOE Response: DOE believes the regulatory coverage, as proposed, contains sufficiently specific and appropriately detailed standards, while still allowing flexibility in the development and implementation of systems designed against performance criteria set forth in the clause.

Comment: A commenter believes that the statement in the NOPR that the proposed rule is not subject to the Paperwork Reduction Act is in error and argues that the proposed rule mandates extensive recordkeeping and is, therefore, a collection of information as that term is defined in the Paperwork Reduction Act.

DOE Response: DOE disagrees, as the requirements for those management controls do not necessarily mandate creation of a new separate system of controls, merely the effective coordination and integration of existing systems, if those are already sufficient. DOE notes that this same commenter also argues that the rule is not needed as there are already such control systems in place and functioning.

Comment: A commenter suggests that DOE articulate the elements of a system which would likely result in DOE's approval.

DOE Response: DOE believes that the detailed performance criteria listed in the proposed clause sufficiently and clearly articulates the system needed to obtain DOE's approval.

Comment: A commenter states that the proposed DEAR 970.0901(a) requires compliance with specifications without requiring the listing of such specifications in the contract.

DOE Response: DEAR 970.0901(a) is a policy statement and a general direction to the contracting officer, as to the general requirements under this subsection. It does not require compliance to specifications.

Comment: A commenter suggested eliminating the reference at DEAR 970.0901(b)(10) to the Comptroller General standards for internal control, as the M&O contractors may not be able to have visibility into changes, nor the ability to comment on or impact these standards.

DOE Response: DOE disagrees with eliminating reference to the Comptroller General standards, as these are readily available and establish basic provisions that are appropriate and desired by DOE in internal control systems. For greater clarity, we have revised that subpart to provide a more exact reference.

Comment: A commenter did not think that reference to "a baseline program of quality assurance" was sufficiently clear.

DOE Response: DOE disagrees, as the referred to sentence in DEAR 970.0901(c) goes on to explain clearly what is required.

Comment: A commenter states that the requirement for internal audit review of the management system and internal controls is a considerable expansion in work and recordkeeping over what is currently being done.

DOE Response: DOE is troubled that a major contractor would currently have in place an internal audit program that did not routinely determine that these systems are accomplishing their objectives and that their controls are working effectively. DOE believes this to be already required and, hence, does not constitute an expansion.

List of Subjects in 48 CFR Part 970

Government procurement.

For the reasons set out in the preamble, part 970 of title 48 of the code

of Federal Regulations is amended as set forth below.

Berton J. Roth,

Acting Director, Office of Procurement, Assistance and Program Management.

Title 48 CFR Chapter 9 is amended as set forth below:

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

1. The authority citation for part 970 continues to read as follows:

Authority: Sec. 161 of the Atomic Energy Act of 1954 (42 U.S.C. 2201), sec. 644 of the Department of Energy Organization Act, Pub. L. 95-91 (42 U.S.C. 7254), sec. 201 of the Federal Civilian Employee and Contractor Travel Expenses Act of 1985 (41 U.S.C. 420) and sec. 1534 of the Department of Defense Authorization Act, 1986, Pub. L. 99-145 (42 U.S.C. 7256a), as amended.

2. Part 970 is amended by adding a new § 970.0901, Management Controls, to read as follows:

970.0901 Management controls.

(a) As a management and operating contractor, the contractor shall develop and maintain systems of management and quality control to discourage waste, abuse, and fraud; and to ensure components, products, and services provided DOE meet's the specifications.

(b) As a part of the required overall management structure, the contractor must maintain management control systems which:

(1) Are documented and satisfactory to DOE;

(2) Ensure that all levels of management are accountable for effective management systems and internal controls within their areas of assigned responsibility;

(3) Cover both programmatic and administrative functions;

(4) Provide reasonable assurance that Government resources are safeguarded against theft, fraud, waste, and unauthorized use;

(5) Promote efficient and effective operations;

(6) Ensure that all obligations and costs incurred are in compliance with the contract's terms and conditions and intended purposes;

(7) Properly record, manage, and report all revenues, expenditures, transactions and assets;

(8) Maintain financial, statistical and other reports necessary to maintain accurate, reliable, and timely accountability and management controls;

(9) Are periodically reviewed to ensure they are adequate to provide reasonable assurance that the objectives of the system are being accomplished and that these controls are working effectively;

(10) Are in accordance with the Comptroller General's standards for internal controls, as set forth in the General Accounting Office Policy and Procedures Manual For Guidance To Federal Agencies, chapter 3 of title 2 (Oct 1984), as amended.

(c) As a management and operating contractor, the contractor shall also develop and maintain a baseline program of quality assurance that will implement documented performance and quality standards, and management controls and assessment techniques to ensure components, services, and products meet DOE's, design agency and other governing and applicable specifications.

3. A new § 970.5204-20 is added to read as follows:

970.5204-20 Management controls.

(a) The contractor shall be responsible for maintaining, as an integral part of its organization, effective systems of management controls for both administrative and programmatic functions. Management controls comprise the plan of organization, methods and procedures adopted by management to reasonably ensure that: The mission and functions assigned to the contractor are properly executed; efficient and effective operations are promoted; resources are safeguarded against theft, fraud, waste, and unauthorized use; all obligations and costs that are incurred under the contract are in compliance with applicable clauses and other current terms, conditions, and intended purposes; all revenues, expenditures, and all other transactions and assets are properly recorded, managed, and reported; and financial, statistical, and other reports necessary to maintain accountability and managerial control are accurate, reliable, and timely. The systems of controls employed by the contractor shall be documented and satisfactory to DOE. Such systems shall be an integral part of the contractor's management functions, including defining specific roles and responsibilities for each level of management, and holding employees accountable for the adequacy of the management systems and internal controls in their areas of assigned responsibility. The contractor shall, as part of the internal audit program required elsewhere in this contract, periodically review the management systems and internal controls employed in programs and administrative areas to ensure that they are adequate to provide reasonable assurance that the objectives of the system are being accomplished and that these systems and controls are working effectively.

(b) The contractor shall be responsible for maintaining, as a part of its operational responsibilities, a baseline quality assurance program that implements documented performance, quality standards, and control and assessment techniques.

[FR Doc. 91-30078 Filed 12-16-91; 8:45 am]

BILLING CODE 6450-01-M

Proposed Rules

Federal Register
Vol. 56, No. 242
Tuesday, December 17, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 979

[Docket No. FV-91-450]

South Texas Melons; Amended Expenses and Establishment of Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would increase the level of authorized expenses and establish the assessment rate under Marketing Order No. 979 for the 1991–92 fiscal period. Authorization of this budget would permit the South Texas Melon Committee (committee) to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessment on handlers.

DATES: Comments must be received by December 31, 1991.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456. Comments should reference the docket number and the date and page number of this issue of the Federal Register and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Martha Sue Clerk, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456, telephone 202–720–2020.

SUPPLEMENTARY INFORMATION: This rule is proposed under Marketing Agreement No. 156 and Order No. 979 (7 CFR Part 979), regulating the handling of melons grown in South Texas. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This rule has been reviewed by the Department of Agriculture in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 27 handlers of South Texas melons under this marketing order, and approximately 27 producers. Small agricultural producers have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of South Texas melon producers and handlers may be classified as small entities.

The budget of expenses for the 1991–92 fiscal period was prepared by the South Texas Melon Committee, the agency responsible for local administration of the marketing order, and submitted to the Department of Agriculture for approval. The members of the committee are handlers and producers of South Texas melons. They are familiar with the committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the committee was derived by dividing anticipated expenses by expected shipments of South Texas melons. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the committee's expenses.

Committee administrative expenses of $93,187, recommended in a mail vote completed September 19, 1991, were approved on November 13, 1991, and published in the Federal Register on November 19, 1991, (56 FR 58302). The committee subsequently met on November 18, 1991, and unanimously recommended funding for several research and promotion projects and adjustments to a number of the previously approved administrative items. The 1991–92 budget of $285,309.51 is $6,180.51 more than the previous year. Major increases in the manager and field salaries, rent and utilities, field travel, and research categories would be partially offset by decreases in the office salary and promotion categories.

The Committee also unanimously recommended an assessment rate of $0.05 per carton of melons, $0.01 more than last season. This rate, when applied to anticipated shipments of 6 million cartons of melons, would yield $300,000 in assessment income. This would be adequate to cover budgeted expenses. Funds in the reserve as of October 31, 1991, estimated at $287,210.22, were within the maximum permitted by the order of two fiscal periods' expenses.

While this action would impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

This action should be expedited because the committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis. The 1991–92 fiscal period for the program began on October 1, 1991, and the marketing order requires that the rate of assessment for the fiscal period apply to all assessable South Texas melons handled during the fiscal period. In addition, handlers are aware of this action which was recommended by the committee at a public meeting.

Therefore, it is found and determined that a comment period of 10 days is appropriate because the amended budget and assessment rate approval for this program needs to be expedited.

List of Subjects in 7 CFR Part 979

Marketing agreements, Melons, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 979 be amended as follows:

PART 979—MELONS GROWN IN SOUTH TEXAS

1. The authority citation for 7 CFR part 979 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Section 979.214 is revised to read as follows:

§ 979.214 Expenses and assessment rate.

Expenses of $285,309.51 by the South Texas Melon Committee are authorized and an assessment rate of $0.05 per carton of regulated melons is established for the fiscal period ending September 30, 1992. Unexpended funds may be carried over as a reserve.

Dated: December 11, 1991.

William J. Doyle

Associate Deputy Director, Fruit and Vegetable Division.

[FR Doc. 91–29990 Filed 12–16–91; 8:45 am]

BILLING CODE 3410-02-M

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7 CFR Part 1205

[CN-91-002]

Amendment to the Cotton Board Rules and Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service proposes to amend the Cotton Board Rules and Regulations in order to implement recent amendments to the Cotton Research and Promotion Order.

These proposed amendments to the rules and regulations would establish procedures for calculating, collecting, and remitting assessments on imported cotton and cotton-containing products.

A de minimis figure based on the value of imported cotton per line item entry would be established to lessen the administrative burden of collecting import assessments while providing for maximum participation of imports of cotton in the assessment provisions. Imported cotton and cotton-containing products containing cotton equal in value or less than the de minimis figure would not be subject to assessment.

Procedures by which refunds of producer assessments are obtained would be removed from the regulations so that the regulations conform to the provisions of the Cotton Research and Promotion Act Amendments of 1990 which eliminated the refund provision.

Exemptions from assessment would be set forth in these amendments to the regulations along with procedures importers would follow to obtain reimbursement of assessments paid on imported cotton and textile products which were not subject to assessment would also be established.

DATES: Written comments concerning the proposed rule must be sent in triplicate and received no later than January 16, 1992.

ADDRESSES: Written comments should be sent to: Craig Shackelford, USDA, AMS, Cotton Division; P.O. Box 96456; room 2641–S; Washington, DC 20090–6456. All comments will be made available for public inspection at the Office of the Docket Clerk during regular business hours. In addition, comments concerning the information collection requirements should be sent to: Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention Desk Officer for Agricultural Marketing Service, USDA. All comments should reference the date and page of the Federal Register publication.

FOR FURTHER INFORMATION CONTACT: Craig Shackelford (202) 720–2259.

SUPPLEMENTARY INFORMATION: This proposal would amend the Cotton Board Rules and Regulations in order to implement the amendments to the Cotton Research and Promotion Order which were issued pursuant to the Cotton Research and Promotion Act Amendments of 1990 enacted by Congress under subtitle G of title XIX of the Food, Agriculture, Conservation and Trade Act of 1990 on November 28, 1990.

A proposed rule amending the Cotton Research and Promotion Order was published for public comment on April 10, 1991. The proposed amendment to the Order was published on July 9, 1991. The proposed amendment was approved by a majority (60 percent) of importers and producers of cotton voting in a referendum conducted July 17–26, and is required to be published in the Federal Register as a final Order amendment.

This proposed rule has been reviewed in accordance with Executive Order 12291 and Departmental Regulation 1512–1 and has been determined to be a non-major rule since it does not meet the criteria for a major regulatory action.

The Administrator, Agricultural Marketing Service (AMS), has certified that this action would not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

There are an estimated 210,000 producers and 650 collecting handlers who are presently subject to rules and regulations issued pursuant to the Cotton Research and Promotion Order. There are also an estimated 10,000 importers that would become subject to the rules and regulations. The majority of these producers, handlers and importers would be classified as small businesses under the criteria established by the Small Business Administration.

Under this proposed amendment, refunds to producers would be eliminated. Therefore, it is estimated that $42,075,853, for 1991, collected by handlers from producers would not be subject to refunds. At current refund rates of approximately 34 percent, $13,965,790 of the estimated $41,075,853 would be retained by the Research and Promotion program. The economic impact of the proposed elimination of refunds is not expected to be significant. It is expected that assessments from imports would total $6,785,816, including reimbursements, and that the total program would generate an estimated total of $47,861,669 based on the 1991 forecast. Therefore, the economic impact of an assessment on importers is not expected to be significant. The economic impact of the other amendments to the regulations as described in the preamble is also not expected to be significant. Furthermore, the Research and Promotion program is expected to benefit producers, handlers and importers by expanding and maintaining new and existing markets.

The proposed rules and regulations impose recordkeeping and reporting burdens on importers and producers. The recordkeeping burden should average approximately .25 hours per year per person. The reporting burden should be approximately 6, 174 hours per year. Therefore, the economic impact of these burdens would not be significant.

Accordingly, the Administrator of the Agricultural Marketing Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

In compliance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork reduction Act (PRA) of 1980 (44 U.S.C. 3501 *et. seq.*) the information collection and

recordkeeping requirements for domestic handlers and producers contained in this subpart have been previously approved by OMB and assigned control number 0581–0093.

Implementation of the provisions of the Cotton Research and Promotion Act Amendments of 1990 would require comparable information collection requirements for importers. The information collection and recordkeeping requirements for importers contained in this subpart have been previously approved by OMB and have also been assigned control number 0581–0093.

Based on comparable research and promotion programs, it would require approximately 10 minutes for an importer to complete a reporting form and approximately 10 minutes to complete a reimbursement or exemption application. There would be an estimated 1,000 importers per year subject to these information collection requirements. Reporting forms would be filed on a monthly basis and reimbursement or exemption applications would be filed when necessary yielding an estimated annual burden of 4080 hours. Importers would be expected to maintain and make available to the Secretary such books and records as necessary to carry out the provisions of the Order and regulations. Importers would be required to retain such records for at least two years beyond the marketing year of their applicability.

Two respondents commented on the proposed reporting and recordkeeping requirements for importers contained in the proposed Order, published in the Federal Register on April 10, 1991 (FR 14482). The comments expressed concerns that the proposed requirements may be overly burdensome, overly broad and violative of the Paperwork Reduction Act.

The agency disagreed and responded by stating that the U.S. Customs Service would as the collecting agency for import assessments. Almost all information required under this proposal would be available from records already maintained by importers under the Customs Service requirements. The Department intends to rely greatly on records maintained by the Customs Service and records maintained by importers under Customs Service requirements for its administration and enforcement of the provisions of the proposed regulations. We anticipate that importers would be required to provide additional reports and records only on occasions when additional information is needed as evidence or reimbursement of assessments.

Comments concerning the information collection requirements contained in this action should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Attention: Desk Officer for Agricultural Marketing Service, USDA.

This proposal is promulgated to implement the Cotton Research and Promotion Act Amendments of 1990 and provisions of the amended Cotton Research and Promotion Order. The proposed amendments to the Cotton Board Rules and Regulations are discussed in the following paragraphs which are arranged by subject.

Definitions

The terms "importer", "import", "cotton", "industrial products", and "Customs Service" would be defined in Section 1205.500.

General

Section 1205.505 "Communication" would be amended by removing the term "refund" and replacing it with the term "reimbursement".

Assessments

Section 1205.510 "Levy of assessments" would be amended by adding the title "Producer assessments" to paragraph (a), redesignating paragraphs (b) and (c) as (a)(1) and (a)(2) respectively, and adding a new paragraph (b)(1) through (b)(6) to provide for importer assessments. The manner in which importer assessments would be determined, the amounts of assessment, and the supplemental assessment for imported cotton would be established. The proposed amendments to the regulations would also contain the procedures for collecting importer assessments. The assessment rate on imported cotton would be $1 per bale. For the purpose of assessing imported cotton or the cotton content of imported products, a bale of cotton would be equivalent to 500 pounds or 226.8 kilograms. The $1 per bale assessment would be converted to a value per kilogram to facilitate the U.S. Customs Service in collecting assessments on the cotton content of imported products.

The supplemental assessment on imported cotton and the cotton content of imported products would be levied at six tenths of one percent of the historical value of the cotton. A supplemental assessment of six tenths of one percent of the value of the cotton is currently levied on domestically produced cotton.

The average price received by producers for a calendar year for Upland cotton in the U.S. weighted by monthly marketings would be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton. This would approximate as nearly as is practical the value of domestically produced cotton and insure that supplemental assessments to be paid by importers are determined in a fair and equitable manner. The average price received by U.S. farmers weighted by marketings for the calendar year 1990 was 65.6 cents per pound or 1.446 dollars per kilogram. The figure of 1.446 dollars per kilogram would be used as the value of imported cotton for the purpose of the assessment calculation for imported cotton during the calendar year 1992. This value would be calculated annually by the Secretary and published in this subpart. The average price of 65.6 cents per pound for calendar year 1990 was obtained from Agricultural Prices, a publication of the National Agricultural Statistics Service of the Department of Agriculture.

Several years ago, the United States converted to the eleven digit Harmonized Tariff Schedule (HTS) in classifying imports. The USDA has published data on the raw fiber content of textile imports for over 20 years. For over 2000 cotton-containing HTS classifications, conversion factors have been developed and updated by the USDA to determine the raw fiber equivalence contained in the end product. These factors are utilized for a variety of purposes including estimating the raw fiber content equivalence of cotton imported into the U.S. The agency proposes to use these conversion factors to reflect the cotton content of imported cotton products for assessment purposes. These conversion factors were compiled by the Economic Research Service of the USDA through extensive contacts with textile manufacturers and represent the predominant raw fiber cotton equivalents for the specific HTS classifications.

The agency has determined that the use of these factors is justified in view of alternatives. For example, the anticipated burden resulting from calculating cotton content for each individual product prior to entry would make such an alternative costly, undesirable, and impractical.

A table would list the HTS classification numbers representing imported cotton and cotton-containing products subject to assessment, the conversion factors, and the assessment per kilogram for each product, except in the case of raw cotton, for which there would be no conversion factor in the

table. HTS classification numbers would be listed in the left hands column of the table.

In determining which HTS classifications would be assessed under this proposal, the primary objectives were to meet the intent of the Cotton Research and Promotion Act Amendments of 1990 by maximizing participation of cotton imports in the assessment provision of the Act, while at the same time, minimizing the burden of administering those provisions. More than 2,400 HTS textile classifications contain cotton. However, out of this total, approximately 700 classifications account for approximately 97 percent of the annual volume of imported cotton textiles and apparel. The agency determined to propose limiting assessments to this lower number, thereby exempting a large number of low volume categories.

The cotton content of industrial products is also not subject to assessment. Industrial products would include such cotton-containing items as tubes, pipes, hoses, belting material, and tires, all of which are reinforced with or in some way composed, in part, of cotton but, are not classified under the HTS textile classification numbers. Certain cotton-containing textiles would also be considered industrial products, and would therefore not be included in the table listing products subject to assessments. Such products would include textile products classified in chapter 59 of the Harmonized Tariff Schedule that include cotton-containing textile fabrics coated, impregnated, covered, or laminated with other materials, textile piping and tubing, and belting.

By limiting the assessment to the 700 HTS classifications, the administrative burdens on all those who are involved in the assessment program would be reduced. At the same time, the vast majority of the volume of cotton textiles and apparel imported into the U.S. would be assessed.

The corresponding conversion factor for each HTS classification number would be listed in the center column of the table in the regulations listing classifications of imported cotton and cotton-containing products subject to assessment. The total assessment per kilogram for each HTS number would be indicated in the right hand column. The total assessment per kilogram would be applied to the net weight of the product entered on the Customs entry documentation form and would take into account the cotton content of each kilogram.

An example of the table is as follows:

HTS classification	Conversion factor	Cents/kg
6205202065 ..... (Mens cotton shirts)	0.9961	1.3035

The assessment per kilogram (not including the conversion factor) represents the sum of the assessment and the supplemental assessment. An example of how the assessment per kilogram would be calculated is as follows.

One bale is equal to 500 pounds.
One kilogram equals 2.2046 pounds.
One pound equals 0.453597 kilograms.
One dollar per bale assessment converted to kilograms:
A 500 pound bale = 226.8 kg. (500 × .453597)
$1 per bale assessment = $0.002000 per pound (1 ÷ 500) = $0.004409 per kg. (1 ÷ 226.8).
Supplemental assessment of 6/10 of 1 percent of the value of the cotton converted to kilograms:
Average price received or average value = $0.656 per pound = $1.446218 per kg. (0.656 × 2.2046)
6/10 of one percent of the average price in kg. = $0.008677 per kg. (1.446 × .006).
Total assessment per kilogram:

$1 per bale equivalent assessment	= $0.004409	per kg.
Supplemental assessment	+ $0.008677	per kg.
total assessment per kg.	= $0.013086	

The total assessment per kilogram in the right hand column of the table would be the product of the conversion factor for the HTS classification and the base assessment per kilogram calculated above. An example would be: HTS code, 6205202065 (Men's Cotton Shirts)

conversion factor	0.9961	
assessment per kg.	× 1.3086	cents
total assessment	= 1.3035	cents per kg.

Prior to the publication of this proposal, the Agency received comments from importers and from others, including the U.S. Customs Service regarding the payment of assessments on domestically produced cotton reimported into the U.S. The 1990 Act Amendments provide that the Secretary shall establish procedures to ensure that the Upland cotton content of imported products is not subject to more than one assessment under this title.

One suggestion from an importer was to reduce the assessment rate by the percentage of U.S. produced cotton exported to the U.S. from foreign countries, or reduce the assessment by a percentage equal to the average return rate of U.S. produced cotton. In 1983 and again in 1987, the Economic Research Service of the USDA published reports identifying raw fiber equivalents of U.S. textile imports, by country of origin. The reports listed the return rates for U.S. produced cotton from 28 countries. The basic assumption made to support the estimates was that the proportion of foreign mill use of U.S. produced cotton was assumed to represent the return ratio for foreign textile products. This was said to be valid in textile producing countries where very little semi-processed fabric is imported for apparel manufacture and subsequent export. However, the import and export of semi-processed products appears to be on the increase globally. Additional calculations and assumptions were made to account for the movement of semi-processed products.

The U.S. Customs Service, which would collect the assessments on imported cotton, expressed concern over implementation of a collection system with assessment rates dependent upon the country of origin. Customs Service representatives have informed us that computer software development for such a system of varying rates would present very difficult problems.

It was the view of some importers, that under a system with assessment rates varying by country of origin the potential exist for substantial handling cost per line item entry being passed to the importer. Presumably this potential would be greater in a situation where the importer uses an agent to perform the import transaction.

In the absence of current estimates on the U.S. produced cotton content of textile imports and other pertinent information, the need to minimize administrative cost and burdens, the proposed regulation does not include a reduction in the assessment rate to account for the U.S. produced cotton content in imported cotton products.

Section 1205.510 would provide exemptions from assessments for importers in the following four situations.

The amendments to the Act provide that the term "cotton" shall not include any entry of imported cotton having a weight or value less than any de minimis figure as established by regulation. In the final rule implementing procedures for the conduct of referenda in connection with the Cotton Research

and Promotion Order, a de minimis value of $220.99 per line item entry was established. This de minimis figure reflects only the value of cotton in each line item entry of imported product shown on the Customs Service entry documentation. Eligibility of importers to vote in the referendum conducted in July 1991, which approved the amended Cotton Research and Promotion Order, was in part determined by whether an importer had entered a value of cotton greater than the de minimis amount into the U.S.

The agency established the $220.99 per line item entry de minimis value based on its determination that the amount of estimated assessment collected on a value of cotton which was less than $220.99 would not be sufficient to adequately cover the estimated amount that the U.S. Customs Service would charge for collecting the assessment. According to the amendments to the Act, the Customs Service is to be reimbursed for the reasonable cost of collecting the assessment. The Act further states that the de minimis figure should be such as to minimize the burden in administering the import assessment but still provide for the maximum participation of importers of cotton in the assessment provision. On that basis, the agency viewed the $220.99 de minimis as consistent with the provisions of the Act.

Importers have suggested that the de minimis figure is too low and that it should be raised substantially. A substantial increase in the de minimis value appears unwarranted and would be inconsistent with the Act. Using $220.99 per line item entry as the minimis value of cotton, the minimum assessment collected would be approximately $2.00, which exceeds the anticipated cost of collecting the assessment and which would satisfy the goal of providing for maximum participation of importers of cotton in the assessment program.

Two examples are provided below to show how the de minimis value might effect the payment of assessment.

Example 1

HTS 6205202065, Men's Cotton Shirts:

Net weight		235.50	kg.
Conversion factor	×	0.9961	
Cotton content	=	234.58	kg.
Cotton value per kg.	×	$1.446	
Total cotton value	=	$339.20	

Since the value of the cotton in the line item entry is greater than $220.99 an assessment would be paid. The multiplication of the net weight times the assessment per kilogram from the table reveals the amount of the assessment.

Net weight		234.58	kg.
Assessment per kg.	×	1.3049	cents
Assessment		$ 3.06	

Since $2.00 in assessment would be due on a $220.99 de minimis value of cotton, the importer could calculate the assessment first and then determine whether to pay the assessment or not by noting if the assessment per line item entry is greater than or less than $2.00.

Example 2

This example shows an entry for which no Research and Promotion assessment would be paid because the value of the cotton is not greater than the de minimis value of $220.99.

HTS code, 6205202065, men's cotton shirts:

Net weight		137.2800	kg.
Conversion factor	×	0.9961	
Cotton content	=	136.7446	kg.
Cotton value per kg.	×	$ 1.446	
Total cotton value	=	$197.73	

Entries of HTS classifications identified in the assessment table of this proposal that qualify for informal entry according to regulations issued by the Customs Service would not be subject to assessment.

Section 1205.510 would provide exemption from assessments for specific HTS classifications in which U.S. produced cotton frequently reenters the U.S. Textile articles assembled abroad from U.S. cut and formed fabrics represent a significant number of entries recorded by the Customs Service. These products can reenter the U.S. under special access programs having special Customs statistical notations. Classification of entries, on the Customs entry documentation, identified by HTS numbers beginning with (9802) would identify these products for exemption from assessment at the time of entry.

An importer would be able to obtain an exemption from assessment for cotton and products composed of U.S. produced cotton, or cotton which is other than Upland cotton prior to entry of the products. Exemptions would be made for a specified weight of an HTS classification to be imported during a specified 90 day period. The specified weight of the HTS classification could be imported in more than one shipment, but all such shipments would be imported during the period designated for the exemption. The Cotton Board would assign a numerical designation to the exemption which the importer would include on the Customs entry documentation to indicate exemption for the entry. The exemption number would be valid only for the specified HTS classification, weight, and time period.

The importer would submit documentation supporting the request for exemption to the Cotton Board prior to the estimated date of entry. Documentation submitted by the importer as evidence that the imported product is composed of U.S. produced cotton or cotton which is other than Upland cotton would provide the basis for the exemption.

Documentation should include (1) the name, address, and importer identification number for the importer; (2) the HTS classification of the imported product; (3) weight of the product for which the exemption is sought; (4) estimated date of entry; (5) commercial invoices; (6) documentation indicating the origin or type of the cotton fiber used to produce the imported product; and (7) manufacturer's description of the imported product.

The United States Customs Service of the United States Department of the Treasury would be designated in § 1205.511 as the organization which would collect importer assessments. The agency is currently working with the Customs Service to incorporate assessment calculations into the computerized Customs entry system.

Two new sections, 1205.514 and 1205.515, would indicate the time at which importers would pay the assessment.

Section 1205.514 has been redesignated as 1205.516 and revised to indicate the type of information that may be requested from importers by the Secretary or the Cotton Board. Since the Customs Service would act as the collecting agent for importer assessments, no regularly scheduled reporting to the Cotton Board would be required. The availability of periodic reports from importers could be needed to assist the Cotton Board in resolving any claims that may arise and also for ascertaining compliance.

Section 1205.520 would be revised to eliminate procedures for cotton producers to obtain refunds. This is in accordance with the Cotton Research and Promotion Act Amendments of 1990.

The section as amended would provide the procedure for importers to

obtain a reimbursement for assessments paid on imported cotton or products not subject to assessment. Such cotton and products would include, but would not be limited to the cotton content of imported products that contained U.S. produced cotton or cotton that is other than Upland cotton. The reimbursement would be made for the portion of the assessment paid on said cotton.

Warehouse Receipts

Section 1205.525 "Entry of gin code number" would be amended by removing the date from the section and revising the text for clarity.

Conforming changes and section and paragraph redesignations would also be made in the regulations for the purpose of clarity and organization.

List of Subjects in 7 CFR Part 1205

Advertising, Agricultural research, Cotton, Marketing agreements, Reporting and record keeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1205 is proposed to be amended as follows:

PART 1205—COTTON RESEARCH AND PROMOTION

1. The authority citation for part 1205 continues to read as follows:

Authority: 7 USC 2101–2118.

2. The authority citation for subpart Cotton Board Rules and Regulations is removed.

3. Section 1205.500 "Terms defined" is amended by adding paragraphs (o), (p), (q), and (r) to read as follows:

Definitions

§ 1205.500 Terms defined.

* * * * *

(o) *Importer* means any person who enters, or withdraws from warehouse, cotton for consumption in the customs territory of the United States and *import* means any such entry.

(p) *Customs Service* means the United States Customs Service of the United States Department of Treasury.

(q) *Cotton* means:

(1) all Upland cotton harvested in the United States, and, except as used in section 7(e) of the Act, includes cottonseed of such cotton and the products derived from such cotton and its seed, and

(2) imports of Upland cotton, including the Upland cotton content of the products derived thereof. The term *cotton* shall not, however, include

(i) any entry of imported cotton by an importer which has a value or weight less than a de minimis amount established in regulations issued by the Secretary and

(ii) industrial products as that term is defined by regulation.

(r) *Industrial products* means cotton-containing products which are classified in the Harmonized Tariff Schedule of the United States under classifications other than textile classifications. Certain cotton-containing textile products under textile classifications shall also be considered to be industrial products, and are therefore not included in the table appearing in these regulations as products subject to assessment. Such products include, but are not limited to textile fabrics coated, impregnated, covered, or laminated, with other materials, textile piping and tubing, and belting materials.

General

4. Section 1205.505 "Communication" is revised to read as follows:

§ 1205.505 Communication.

All reports, request, applications for reimbursements, and communications in connection with the Cotton Research and Promotion Order shall be addressed as follows: Cotton Board, Post Office Box 2121, Memphis, Tennessee, 38101–2121.

Assessments

5. Section 1205.510 "Levy of assessments" is revised to read as follows:

§ 1205.510 Levy of assessments.

(a) *Producer assessments.* An assessment of $1 per bale for cotton research and promotion is hereby levied on each bale of Upland cotton that is produced from cotton harvested and ginned except cotton consumed by any governmental agency from its own production. Such assessment shall be payable and collected only once on each bale.

(1) A supplemental assessment for cotton research and promotion in addition to the $1 per bale assessment provided for in paragraph (a) of this section, is hereby levied on each bale of Upland cotton harvested and ginned except cotton consumed by any governmental agency from its own production. The supplemental assessment rate shall be levied at the rate of six-tenths of one percent of:

(i) The current value of the cotton multiplied by the number of pounds of lint cotton or;

(ii) The current value of the cotton converted to a fixed amount per bale as reflected in the following assessment chart:

ASSESSMENT CHART [1]

Current value (cents per pound)	Supplemental assessment, dollars per bale
.00 to 9.99	.15
10.00 to 19.99	.45
20.00 to 29.99	.75
30.00 to 39.99	1.05
40.00 to 49.99	1.35
50.00 to 59.99	1.65
60.00 to 69.99	1.95
70.00 to 79.99	2.25
80.00 to 89.99	2.55
90.00 to 99.99	2.85
100.00 to 109.99	3.15
110.00 to 119.99	3.45

[1] Assessment is calculated in 6/10 of 1 percent of the midpoint of each 10¢ increment, based on a 500 lb. bale and converted to a fixed amount per bale.

(2) Each marketing year the collecting handler must select one of the two options for collecting the supplemental assessment as provided in paragraph (a)(1) of this section. The handler shall notify the Cotton Board as to the method selected at the time the handler files the first handler report each marketing year.

(b) Importer assessment. An assessment for cotton research and promotion of $1 per bale is hereby levied on each bale of cotton, or the bale equivalent thereof for cotton in cotton-containing products identified in the HTS conversion factor table in paragraph (b)(3) of this section and imported into the United States on or after (insert effective date of final rule). The $1 per bale assessment shall be converted to a fixed amount per kilogram to facilitate the U.S. Customs Service in collecting this assessment.

(1) A supplemental assessment for cotton research and promotion in addition to the $1 per bale assessment provided for in paragraph (b) of this section is hereby levied on each bale of cotton or bale equivalent of cotton in cotton-containing products, identified in this subpart, imported into the United States on or after (insert effective date of final rule). The supplemental assessment shall be levied at the rate of 6/10 of 1 percent of the historical value of cotton as determined by the Secretary. The rate of the supplemental assessment on imported cotton will be the same as that levied on cotton produced within the United States. The supplemental assessment will be calculated as a fixed amount per kilogram and added to the $1 per bale or bale equivalent assessment to facilitate the Customs Service in collecting assessments.

(2) The average of monthly average prices received by U.S. farmers will be calculated annually. Such average will be used as the value of imported cotton

for the purpose of levying the supplemental assessment on imported cotton and will be expressed in kilograms. The value of imported cotton for the purpose of levying this supplemental assessment for the period January 1, 1992 through December 31, 1992 is $1.446 per kilogram.

(3) The following table contains the Harmonized Tariff Schedule classification numbers and corresponding conversion factors and assessments. The left column of the table indicates the HTS classifications of imported cotton and cotton-containing products subject to assessment. The center column indicates the conversion factor for determining the raw fiber content for each kilogram of the HTS. HTS numbers for raw cotton have no conversion factor in the table. The right column indicates the total assessment per kilogram of the article assessed. Any line item entry of cotton appearing on Customs entry documentation in which the value of the cotton contained therein is less than $220.99 will not be subject to assessments as described in this section.

IMPORT ASSESSMENT TABLE

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
5201001000	.0000	1.3086
5201002000	.0000	1.3086
5201002010	.0000	1.3086
5201002020	.0000	1.3086
5201002050	.0000	1.3086
5204110000	1.1111	1.4540
5204200000	1.1111	1.4540
5205111000	1.1111	1.4540
5205121000	1.1111	1.4540
5205122000	1.1111	1.4540
5205131000	1.1111	1.4540
5205141000	1.1111	1.4540
5205210000	1.1111	1.4540
5205220000	1.1111	1.4540
5205230000	1.1111	1.4540
5205240000	1.1111	1.4540
5205250000	1.1111	1.4540
5205310000	1.1111	1.4540
5205320000	1.1111	1.4540
5205330000	1.1111	1.4540
5205340000	1.1111	1.4540
5205410000	1.1111	1.4540
5205440000	1.1111	1.4540
5206120000	0.5556	0.7271
5206130000	0.5556	0.7271
5206140000	0.5556	0.7271
5206230000	0.5556	0.7271
5206240000	0.5556	0.7271
5206310000	0.5556	0.7271
5207100000	1.1111	1.4540
5208112040	1.1455	1.4990
5208112090	1.1455	1.4990
5208114060	1.1455	1.4990
5208124020	1.1455	1.4990
5208124040	1.1455	1.4990
5208124090	1.1455	1.4990
5208126020	1.1455	1.4990
5208126040	1.1455	1.4990
5208126060	1.1455	1.4990
5208128020	1.1455	1.4990

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
5208128090	1.1455	1.4990
5208130000	1.1455	1.4990
5208192020	1.1455	1.4990
5208192090	1.1455	1.4990
5208194020	1.1455	1.4990
5208194090	1.1455	1.4990
5208196090	1.1455	1.4990
5208224040	1.1455	1.4990
5208224090	1.1455	1.5006
5208226020	1.1455	1.4990
5208228020	1.1455	1.4990
5208230000	1.1455	1.4990
5208292020	1.1455	1.4990
5208294090	1.1455	1.4990
5208296090	1.1455	1.4990
5208298020	1.1455	1.4990
5208312000	1.1455	1.4990
5208323020	1.1455	1.4990
5208323040	1.1455	1.4990
5208323090	1.1455	1.4990
5208324020	1.1455	1.4990
5208324040	1.1455	1.4990
5208325020	1.1455	1.4990
5208330000	1.1455	1.4990
5208392020	1.1455	1.4990
5208392090	1.1455	1.4990
5208394090	1.1455	1.4990
5208396090	1.1455	1.4990
5208398020	1.1455	1.4990
5208412000	1.1455	1.4990
5208416000	1.1455	1.4990
5208418000	1.1455	1.4990
5208421000	1.1455	1.4990
5208423000	1.1455	1.4990
5208424000	1.1455	1.4990
5208425000	1.1455	1.4990
5208430000	1.1455	1.4990
5208492000	1.1455	1.4990
5208494090	1.1455	1.4990
5208496090	1.1455	1.4990
5208498090	1.1455	1.4990
5208516060	1.1455	1.4990
5208523020	1.1455	1.4990
5208523040	1.1455	1.4990
5208523090	1.1455	1.4990
5208524020	1.1455	1.4990
5208524040	1.1455	1.4990
5208524060	1.1455	1.4990
5208530000	1.1455	1.4990
5208592020	1.1455	1.4990
5208592090	1.1455	1.4990
5208594090	1.1455	1.4990
5208596090	1.1455	1.4990
5209110020	1.1455	1.4990
5209110030	1.1455	1.4990
5209110050	1.1455	1.4990
5209110090	1.1455	1.4990
5209120020	1.1455	1.4990
5209120040	1.1455	1.4990
5209190020	1.1455	1.4990
5209190040	1.1455	1.4990
5209190060	1.1455	1.4990
5209190090	1.1455	1.4990
5209220020	1.1455	1.4990
5209290040	1.1455	1.4990
5209290090	1.1455	1.4990
5209313000	1.1455	1.4990
5209316030	1.1455	1.4990
5209316090	1.1455	1.4990
5209320020	1.1455	1.4990
5209320040	1.1455	1.4990
5209390020	1.1455	1.4990
5209390040	1.1455	1.4990
5209390060	1.1455	1.4990
5209390080	1.1455	1.4990
5209390090	1.1455	1.4990
5209413000	1.1455	1.4990

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
5209416020	1.1455	1.4990
5209420020	1.0309	1.3490
5209420040	1.0309	1.3490
5209430020	1.1455	1.4990
5209430040	1.1455	1.4990
5209490020	1.1455	1.4990
5209490090	1.1455	1.4990
5209516030	1.1455	1.4990
5209516050	1.1455	1.4990
5209590020	1.1455	1.4990
5209590090	1.1455	1.4990
5210114020	0.6873	0.8994
5210114040	0.6873	0.8994
5210116020	0.6873	0.8994
5210116040	0.6873	0.8994
5210116060	0.6873	0.8994
5210120000	0.6873	0.8994
5210192090	0.6873	0.8994
5210216060	0.6873	0.8994
5210314020	0.6873	0.8994
5210316020	0.6873	0.8994
5210318020	0.6873	0.8994
5210416000	0.6873	0.8994
5210418000	0.6873	0.8994
5210514040	0.6873	0.8994
5210516020	0.6873	0.8994
5210516040	0.6873	0.8994
5210516060	0.6873	0.8994
5211190020	0.6873	0.8994
5211190060	0.6873	0.8994
5211290090	0.6873	0.8994
5211390060	0.6873	0.8994
5211490020	0.6873	0.8994
5211490090	0.6873	0.8994
5211590020	0.6873	0.8994
5212236060	0.9164	1.1992
5601101000	1.1455	1.4990
5601102000	1.0413	1.3626
5601210010	1.1455	1.4990
5601210090	1.1455	1.4990
5601220010	1.0413	1.3626
5601220090	1.0413	1.3626
5601290090	0.9730	1.2733
5601300000	1.1455	1.4990
5602109010	1.0629	1.3909
5602109090	0.5727	0.7494
5602210000	1.0629	1.3909
5602290000	1.1455	1.4990
5603001090	1.0413	1.3626
5603009010	0.1041	0.1362
5603009030	0.3124	0.4088
5603009050	0.3124	0.4088
5603009070	0.3124	0.4088
5603009090	0.3124	0.4088
5604900000	0.5556	0.7271
5606000000	0.3030	0.3965
5607100000	0.8791	1.1504
5607210000	0.8791	1.1504
5607290000	0.8791	1.1504
5607301000	0.8791	1.1504
5607302000	0.8791	1.1504
5607411000	0.8081	1.0575
5607413000	0.8081	1.0575
5607491000	0.8081	1.0575
5607491500	0.8081	1.0575
5607492500	0.8081	1.0575
5607493000	0.8081	1.0575
5607502000	0.8081	1.0575
5607504000	0.8081	1.0575
5607902000	0.8889	1.1632
5608110000	1.0101	1.3218
5608110090	1.0101	1.3218
5608191010	1.0101	1.3218
5608191020	1.0101	1.3218
5608192000	1.0101	1.3218
5608901000	1.1111	1.4540
5608902000	1.1111	1.4540

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
5608903000	1.0101	1.3218
5609003000	1.0101	1.3218
5609004000	0.5556	0.7271
5702202000	1.0989	1.4380
5702491010	1.0333	1.3522
5702991010	1.1111	1.4540
5703100000	0.6313	0.8261
5704900000	0.2104	0.2753
5801100000	1.0629	1.3909
5801220000	1.1455	1.4990
5801230000	1.1455	1.4990
5801250010	1.1455	1.4990
5801250020	1.1455	1.4990
5801310000	1.0413	1.3626
5801330000	1.0413	1.3626
5801350010	1.0413	1.3626
5801350020	1.0413	1.3626
5802190000	1.1455	1.4990
5802300030	0.5727	0.7494
5804210000	1.0413	1.3626
5804290020	1.1455	1.4990
5805004090	1.1447	1.4980
5806102000	1.0413	1.3626
5806200000	0.3534	0.4625
5806310000	1.1455	1.4990
5806321010	1.0413	1.3626
5806321090	1.0413	1.3626
5806322000	1.0413	1.3626
5806392000	1.1447	1.4980
5806400000	0.4296	0.5622
5807101020	1.0413	1.3626
5808103010	0.5727	0.7494
5808900010	0.5727	0.7494
5810910020	1.1455	1.4990
5810920040	1.0413	1.3626
5810920080	1.0413	1.3626
5811002000	1.1455	1.4990
5811003000	1.0413	1.3626
6002302000	0.9996	1.3081
6002920000	1.1574	1.5146
6101200010	1.0094	1.3209
6101302010	1.2235	1.6011
6101302020	1.2235	1.6011
6102200010	1.0094	1.3209
6102302010	1.2235	1.6011
6102302020	1.2235	1.6011
6103421020	0.8806	1.1524
6103421040	0.8806	1.1524
6103421050	0.8806	1.1524
6103421070	0.8806	1.1524
6103431520	0.2516	0.3292
6103431540	0.2516	0.3292
6103431550	0.2516	0.3292
6104220040	0.9002	1.1780
6104220060	0.9002	1.1780
6104320000	0.9207	1.2048
6104410010	0.9645	1.2621
6104420010	0.9002	1.1780
6104420020	0.9002	1.1780
6104431010	0.4823	0.6311
6104432010	0.0636	0.0832
6104510000	0.9978	1.3057
6104520010	0.9312	1.2186
6104520020	0.9312	1.2186
6104532010	0.0658	0.0861
6104622010	0.8806	1.1524
6104622025	0.8806	1.1524
6104622030	0.8806	1.1524
6104622060	0.8806	1.1524
6104632010	0.3774	0.4939
6104632025	0.3774	0.4939
6104632030	0.3774	0.4939
6104632060	0.3774	0.4939
6105100010	0.9850	1.2890
6105100020	0.9850	1.2890
6105100030	0.9850	1.2890
6105202010	0.3078	0.4028

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6105202030	0.3078	0.4028
6106100010	0.9850	1.2890
6106100020	0.9850	1.2890
6106100030	0.9850	1.2890
6106202010	0.3078	0.4028
6106202030	0.3078	0.4028
6106901010	0.8080	1.0573
6107110010	1.1322	1.4816
6107110020	1.1322	1.4816
6107120010	0.5032	0.6585
6107210010	0.8806	1.1524
6107220025	0.3774	0.4939
6108110010	1.1314	1.4806
6108210010	1.2445	1.6286
6108210020	1.2445	1.6286
6108220020	1.1314	1.4806
6108220030	1.1314	1.4806
6108310010	1.1201	1.4658
6108320010	0.2489	0.3257
6108320015	0.2489	0.3257
6108320025	0.2489	0.3257
6108910015	1.2445	1.6286
6108910025	1.2445	1.6286
6108910030	1.2445	1.6286
6108920030	0.2489	0.3257
6108994010	1.1790	1.5428
6109100005	0.9956	1.3028
6109100007	0.9956	1.3028
6109100009	0.9956	1.3028
6109100012	0.9956	1.3028
6109100014	0.9956	1.3028
6109100018	0.9956	1.3028
6109100023	0.9956	1.3028
6109100027	0.9956	1.3028
6109100037	0.9956	1.3028
6109100040	0.9956	1.3028
6109100045	0.9956	1.3028
6109100060	0.9956	1.3028
6109100065	0.9956	1.3028
6109100070	0.9956	1.3028
6109901007	0.3111	0.4071
6109901009	0.3111	0.4071
6109901025	0.3111	0.4071
6109901050	0.3111	0.4071
6109901060	0.3111	0.4071
6109901065	0.3111	0.4071
6109901090	0.3111	0.4071
6110101010	1.2330	1.6135
6110101020	1.2330	1.6135
6110102010	0.8631	1.1295
6110102030	0.8631	1.1295
6110102070	0.8631	1.1295
6110102080	0.8631	1.1295
6110202005	1.1837	1.5490
6110202010	1.1837	1.5490
6110202015	1.1837	1.5490
6110202020	1.1837	1.5490
6110202025	1.1837	1.5490
6110202030	1.1837	1.5490
6110202035	1.1837	1.5490
6110202040	1.1574	1.5146
6110202045	1.1574	1.5146
6110202065	1.1574	1.5146
6110202075	1.1574	1.5146
6110301510	0.4932	0.6465
6110301520	0.4932	0.6454
6110301560	0.4932	0.6454
6110303010	0.1850	0.2421
6110303015	0.1850	0.2421
6110303020	0.1850	0.2421
6110303025	0.1850	0.2421
6110303040	0.1850	0.2421
6110303045	0.1850	0.2421
6110303050	0.1850	0.2421
6110303055	0.1850	0.2421
6110900022	0.2630	0.3442
6110900024	0.2630	0.3442

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6110900036	0.3902	0.5106
6110900038	0.3902	0.5106
6110900040	0.2630	0.3442
6110900042	0.2630	0.3442
6110900090	0.2630	0.3442
6111201000	1.2581	1.6463
6111202000	1.2581	1.6463
6111203000	1.0064	1.3170
6111205000	1.0064	1.3170
6111206010	1.0064	1.3170
6111206020	1.0064	1.3170
6111206030	1.0064	1.3170
6111206040	1.0064	1.3170
6111305015	0.2516	0.3292
6111305020	0.2516	0.3292
6111305040	0.2516	0.3292
6112110050	0.7548	0.9877
6112120010	0.2516	0.3292
6112120030	0.2516	0.3292
6112120040	0.2516	0.3292
6112120050	0.2516	0.3292
6112120060	0.2516	0.3292
6112390010	1.1322	1.4816
6112490010	0.9435	1.2347
6113000085	0.4783	0.6259
6114200005	0.9002	1.1780
6114200010	0.9002	1.1780
6114200015	0.9002	1.1780
6114200020	1.2860	1.6829
6114200040	0.9002	1.1780
6114200052	0.9002	1.1780
6114200060	0.9002	1.1780
6114301020	0.2572	0.3366
6114303030	0.2572	0.3366
6114303050	0.2572	0.3366
6115110010	1.0522	1.3769
6115110020	1.0522	1.3769
6115120000	1.0522	1.3769
6115190010	1.0417	1.3632
6115200010	1.0522	1.3769
6115910000	0.8681	1.1360
6115922000	1.0417	1.3632
6115932000	0.2315	0.3029
6116101510	0.3655	0.4783
6116101520	0.8528	1.1160
6116102510	0.3323	0.4348
6116103520	0.7753	1.0146
6116103540	0.8079	1.0572
6116910000	0.9137	1.1957
6116922010	1.0965	1.4349
6116922020	1.0965	1.4349
6116922030	1.2183	1.5943
6116922040	1.0965	1.4349
6116922060	1.2183	1.5943
6116923000	1.0965	1.4349
6116931000	1.1076	1.4494
6116932010	0.1218	0.1594
6116932020	0.1218	0.1594
6117101000	1.0260	1.3452
6117800010	0.9747	1.2755
6117800035	0.3655	0.4783
6117900036	1.1076	1.4494
6117900056	1.1076	1.4494
6201110010	0.9774	1.2790
6201121000	0.9480	1.2406
6201122010	0.8953	1.1716
6201122050	0.6847	0.8960
6201122060	0.6847	0.8960
6201131000	0.9576	1.2531
6201134015	0.2107	0.2757
6201134030	0.2633	0.3446
6201912010	0.9554	1.2502
6201921000	0.9267	1.2127
6201921500	1.1583	1.5158
6201922010	1.0296	1.3473
6201922030	1.2871	1.6843
6201922040	1.2871	1.6843

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6201922050	1.0296	1.3473
6201922060	1.0296	1.3473
6201931000	0.3089	0.4042
6201932020	0.2574	0.3368
6201933000	1.1700	1.5311
6201933510	0.2574	0.3368
6201933520	0.2574	0.3368
6202110010	0.0650	0.0851
6202121000	0.9372	1.2264
6202122010	1.1064	1.4478
6202122025	1.3017	1.7034
6202122050	0.8461	1.1072
6202122060	0.8461	1.1072
6202131000	0.9687	1.2676
6202134005	0.2664	0.3486
6202134020	0.3330	0.4358
6202134030	0.3330	0.4358
6202912010	0.9663	1.2645
6202921000	1.0413	1.3626
6202921500	1.0413	1.3626
6202922025	1.3017	1.7034
6202922060	1.0413	1.3626
6202922070	1.0413	1.3626
6202931000	0.3124	0.4088
6202934500	1.1833	1.5485
6202935010	0.2603	0.3406
6202935020	0.2603	0.3406
6203112000	0.1301	0.1702
6203121000	0.5435	0.7112
6203122010	0.1302	0.1704
6203193000	1.1833	1.5485
6203221000	1.3017	1.7034
6203322010	1.2366	1.6182
6203322040	1.2366	1.6182
6203332010	0.1302	0.1704
6203392010	1.1715	1.5330
6203411010	0.9448	1.2364
6203422010	0.9961	1.3035
6203422025	0.9961	1.3035
6203422050	0.9961	1.3035
6203424005	1.2451	1.6293
6203424010	1.2451	1.6293
6203424015	0.9961	1.3035
6203424020	1.2451	1.6293
6203424025	1.2451	1.6293
6203424030	1.2451	1.6293
6203424035	1.2451	1.6293
6203424040	0.9961	1.3035
6203424045	0.9961	1.3035
6203424050	0.9238	1.2089
6203424060	0.9238	1.2089
6203431500	0.1245	0.1629
6203433010	0.5199	0.6803
6203434010	0.1232	0.1612
6203434020	0.1232	0.1612
6203434030	0.1232	0.1612
6203434040	0.1232	0.1612
6203492010	0.1245	0.1629
6203492030	0.1245	0.1629
6203493045	0.2490	0.3258
6203493060	0.1244	0.1628
6204132010	0.1302	0.1704
6204192000	0.1302	0.1704
6204193090	0.2603	0.3406
6204221000	1.3017	1.7034
6204223030	1.0413	1.3626
6204223040	1.0413	1.3626
6204223050	1.0413	1.3626
6204223060	1.0413	1.3626
6204223065	1.0413	1.3626
6204292015	0.3254	0.4258
6204292040	0.3254	0.4258
6204312010	0.0650	0.0851
6204322030	1.0413	1.3626
6204335010	0.1301	0.1702
6204393010	0.1301	0.1702
6204394040	0.1301	0.1702

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6204394060	0.2603	0.3406
6204423010	1.2728	1.6656
6204423030	0.9546	1.2492
6204423040	0.9546	1.2492
6204423050	0.9546	1.2492
6204423060	0.9546	1.2492
6204434010	0.4724	0.6182
6204434030	0.2953	0.3864
6204434040	0.2953	0.3864
6204444010	0.4831	0.6322
6204490040	0.1301	0.1702
6204490060	0.2603	0.3406
6204522010	1.2654	1.6559
6204522030	1.2654	1.6559
6204522040	1.2654	1.6559
6204522070	1.0656	1.3944
6204522080	1.0656	1.3944
6204533010	0.2664	0.3486
6204593010	0.0666	0.0872
6204594040	0.1331	0.1742
6204594060	0.2664	0.3486
6204610010	0.0623	0.0815
6204622010	0.9961	1.3035
6204622025	0.9961	1.3035
6204622050	0.9961	1.3035
6204624005	1.2451	1.6293
6204624010	1.2451	1.6293
6204624020	0.9961	1.3035
6204624025	1.2451	1.6293
6204624030	1.2451	1.6293
6204624035	1.2451	1.6293
6204624040	1.2451	1.6293
6204624045	0.9961	1.3035
6204624050	0.9961	1.3035
6204624055	0.9854	1.2895
6204624060	0.9854	1.2895
6204624065	0.9854	1.2895
6204633510	0.2546	0.3332
6204633530	0.2546	0.3332
6204633532	0.2437	0.3189
6204633540	0.2437	0.3189
6204692510	0.2490	0.3258
6204692540	0.2437	0.3189
6204693040	0.1244	0.1628
6204699040	0.2490	0.3258
6205202015	0.9961	1.3035
6205202020	0.9961	1.3035
6205202025	0.9961	1.3035
6205202030	0.9961	1.3035
6205202035	1.1206	1.4664
6205202046	0.9961	1.3035
6205202050	0.9961	1.3035
6205202060	0.9961	1.3035
6205202065	0.9961	1.3035
6205202070	0.9961	1.3035
6205202075	0.9961	1.3035
6205302010	0.3113	0.4074
6205302030	0.3113	0.4074
6205302040	0.3113	0.4074
6205302050	0.3113	0.4074
6205302070	0.3113	0.4074
6205302080	0.3113	0.4074
6206100040	0.1245	0.1629
6206303010	0.9961	1.3035
6206303030	0.9961	1.3035
6206303040	0.9961	1.3035
6206303050	0.9961	1.3035
6206303060	0.9961	1.3035
6206403010	0.3113	0.4074
6206403030	0.3113	0.4074
6206403050	0.3113	0.4074
6206900040	0.2490	0.3258
6207110000	1.0852	1.4201
6207190010	0.3617	0.4733
6207210010	1.1085	1.4506
6207210030	1.1085	1.4506
6207220000	0.3695	0.4835

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6207911000	1.1455	1.4990
6208210010	1.0583	1.3849
6208210020	1.0583	1.3849
6208220000	0.1245	0.1629
6208911010	1.1455	1.4990
6208913010	1.1455	1.4990
6208920010	0.1273	0.1666
6208920030	0.1273	0.1666
6208996030	1.0965	1.4349
6209201000	1.1577	1.5150
6209203000	0.9749	1.2758
6209205030	0.9749	1.2758
6209205035	0.9749	1.2758
6209205040	1.2186	1.5947
6209205045	0.9749	1.2758
6209205050	0.9749	1.2758
6209303020	0.2463	0.3223
6209303040	0.2463	0.3223
6210104015	0.2291	0.2998
6210301020	0.0891	0.1166
6210401010	0.0391	0.0512
6210401020	0.4556	0.5962
6210401030	0.4556	0.5962
6210501020	0.0911	0.1192
6211111010	0.1273	0.1666
6211111020	0.1273	0.1666
6211112010	1.1455	1.4990
6211112020	1.1455	1.4990
6211201535	0.2473	0.3236
6211320010	1.0413	1.3626
6211320015	1.0413	1.3626
6211320030	0.9763	1.2776
6211320060	0.9763	1.2776
6211320070	0.9763	1.2776
6211320080	0.9763	1.2776
6211330010	0.3254	0.4258
6211330030	0.3905	0.5110
6211330035	0.3905	0.5110
6211330040	0.3905	0.5110
6211330050	0.3905	0.5110
6211420010	1.0413	1.3626
6211420020	1.0413	1.3626
6211420025	1.1715	1.5330
6211420050	1.1715	1.5330
6211420060	1.0413	1.3626
6211420070	1.1715	1.5330
6211420080	1.1715	1.5330
6211430010	0.2603	0.3406
6211430030	0.2603	0.3406
6211430060	0.2603	0.3406
6211430090	0.2603	0.3406
6211490010	1.1214	1.4675
6212101020	0.2412	0.3156
6212102010	0.9646	1.2623
6212102020	0.2412	0.3156
6212200020	0.3014	0.3944
6212900010	0.7717	1.0098
6212900030	0.1929	0.2524
6213201000	1.1809	1.5453
6213202000	1.0628	1.3908
6213901000	0.4724	0.6182
6214101000	1.0965	1.4349
6214200000	0.8951	1.1713
6214300000	0.1206	0.1578
6214900010	0.9043	1.1834
6215100040	0.9234	1.2084
6216001000	0.3617	0.4733
6216001510	0.3617	0.4733
6216002540	0.1743	0.2281
6216003810	1.2451	1.6293
6216003820	1.2451	1.6293
6216004400	0.5659	0.7405
6216004835	1.1319	1.4812
6216004845	1.1319	1.4812
6216006000	1.2442	1.6282
6217100010	1.0182	1.3324
6217100030	0.2546	0.3332

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS classification	Conversion factor	Cents/KG.
6217900075	1.0182	1.3324
6301200010	0.9219	1.2064
6301300010	0.8766	1.1471
6301300020	0.8766	1.1471
6301400010	1.0626	1.3905
6301400020	1.0626	1.3905
6302100010	1.1689	1.5296
6302212010	1.1689	1.5296
6302212020	0.8182	1.0707
6302212030	1.1689	1.5296
6302212040	0.8182	1.0707
6302212060	0.8182	1.0707
6302222010	0.4091	0.5353
6302222020	0.4091	0.5353
6302311060	0.8182	1.0707
6302311090	0.8182	1.0707
6302312010	1.1689	1.5296
6302312020	0.8182	1.0707
6302312030	1.1689	1.5296
6302312040	0.8182	1.0707
6302312050	0.8182	1.0707
6302312060	0.8182	1.0707
6302312090	0.8182	1.0707
6302322020	0.4091	0.5353
6302322040	0.4091	0.5353
6302402010	0.9935	1.3001
6302402020	1.0626	1.3905
6302511000	0.5844	0.7647
6302512000	0.8766	1.1471
6302513000	0.5844	0.7647
6302514000	0.8182	1.0707
6302530010	1.0626	1.3905
6302530020	1.0626	1.3905
6302530030	1.0626	1.3905
6302590000	1.1189	1.4642
6302600010	1.1689	1.5296
6302600020	1.0520	1.3766
6302600030	1.0520	1.3766
6302910005	1.0520	1.3766
6302910015	1.1689	1.5296
6302910025	1.0520	1.3766
6302910035	1.0520	1.3766
6302910045	1.0520	1.3766
6302910050	1.0520	1.3766
6302910060	1.0520	1.3766
6303110000	0.9248	1.2102
6303120000	1.0626	1.3905
6303910000	0.6429	0.8413
6303920000	0.2922	0.3824
6304111000	1.0404	1.3615
6304112000	1.0626	1.3905
6304190500	1.0520	1.3766
6304191000	1.1689	1.5296
6304191500	0.4091	0.5353
6304192000	0.4091	0.5353
6304910020	0.9351	1.2237
6304910040	1.0626	1.3905
6304920000	0.9351	1.2237
6304930000	1.0626	1.3905
6304992000	1.1680	1.5284

(4) Any entry of cotton that qualifies for informal entry according to regulations issued by the Customs Service will not be subject to the assessment.

(5) Imported textile articles assembled abroad in whole or in part of fabricated components, produced in the United States which:

(i) Were exported from the U.S. in condition ready for assembly without further fabrication,

(ii) Have not lost their physical identity in such articles by change in form, shape or otherwise, and

(iii) Have not been advanced in value or improved in condition abroad except by being assembled and except by operations incidental to the assembly process shall not be subject to assessments under this subpart. The specific HTS categories affected under this paragraph are 9802.00.8010, 9802.00.8040, and 9802.00.8060.

(6) Imported cotton and products may be exempted by the Cotton Board from assessment under this paragraph. Such imported cotton and products may include, but are not limited to cotton and the cotton content of products which is U.S. produced cotton, or cotton other than Upland cotton.

(i) A request for such exemption must be submitted to the Cotton Board by the importer, prior to the importation of the cotton or cotton product. The Cotton Board will then issue, if deemed appropriate, a numbered certificate. The exemption number should be entered on the Customs entry documentation.

(ii) The request for exemption should include:

(A) The name, address, and importer identification number for the importer;

(B) The HTS classification of the imported product;

(C) Weight of the product for which the exemption is sought;

(D) Estimated date of entry;

(E) Commercial invoices or other such documentation indicating the origin of production or type of the cotton fiber used to produce the imported product;

(F) Manufacturer's descriptions of the imported product.

6. Section 1205.511 "Payment and collection" is revised to read as follows:

§ 1205.511 Payment and collection.

(a) The $1 per bale assessment shall be paid by:

(1) The producer of the cotton to the collecting handler designated in § 1205.512, and

(2) The importer of cotton to the Customs Service as provided in § 1205.513.

(b) The supplemental assessment shall be paid by:

(1) The producer of the cotton to the collecting handler designated in § 1205.514, and

(2) The importer of cotton to the Customs Service as described in § 1205.515.

(c) If more than one person subject to assessment shares in the proceeds received from a bale or bale equivalent, each such person is obligated to pay that portion of the assessment that is equivalent to that person's proportionate share of the proceeds.

(d) Failure of the handler to collect the assessments on each bale shall not relieve the handler of the handler's obligation to remit the assessments to the Cotton Board as required in §§ 1205.512, 1205.513 and 1205.516.

7. In § 1205.512 "Collecting handlers and the time of collection of $1 per bale assessment" paragraph (h) is revised to read as follows:

§ 1205.512 Collecting handlers and the time of collection of the $1 per bale assessment.

Collecting handlers and the time of collecting the $1 per bale assessment shall be as follows:

* * * * *

(h) In the event of a producer's death, bankruptcy, receivership, or incapacity to act, the representative of such producer, or the producer's estate, or the person acting on behalf of creditors, shall be considered the producer for the purposes of this section.

8. In § 1205.513 "Collecting handlers and time of collection of the supplemental assessment" paragraph (k) is revised to read as follows:

§ 1205.513 Collecting handlers and the time of collection of the supplemental assessment

* * * * *

(k) In the event of a producer's death, bankruptcy, receivership, or incapacity to act, the representative of such producer or the producer's estate, or the person acting on behalf of creditors, shall be considered the producer for the purposes of this section.

§ 1205.516 [Redesignated as § 1205.518]

9. Section 1205.516 "Receipts for payment of assessments" is redesignated as § 1205.518.

§ 1205.514 [Redesignated as § 1205.516]

10. Section 1205.514 "Reports and remittance to the Cotton Board" is redesignated as § 1205.516 and revised to read as follows:

§ 1205.516 Reports and remittance to the Cotton Board.

(a) *Handler Reports and Remittances.* Each collecting handler shall transmit assessments to the Cotton Board as follows:

(1) *Reporting periods.* Each calendar month shall be a reporting period and the period shall end on the close of business on the last day of the month.

(2) *Reports.* Each collecting handler shall make reports on forms made available or approved by the Cotton Board. Each report shall be mailed to the

Cotton Board and postmarked within 10 days after the close of the reporting period.

(i) *Collecting handler report.* Each collecting handler shall prepare a separate report form each reporting period for each gin from which such handler handles cotton on which the handler is required to collect the assessments during the reporting period. Each report shall be mailed in duplicate to the Cotton Board and shall contain the following information:

(A) Date of report;

(B) Reporting period covered by report;

(C) Gin code number;

(D) Name and address of handler;

(E) Listing of all producers from whom the handler was required to collect the assessments, their addresses, total number of bales, and total assessment collected and remitted for each producer;

(F) Date of last report remitting assessments to the Cotton Board.

(ii) *No Cotton Purchased Report.* Each collecting handler shall submit a no cotton purchased report form for each reporting period in which no cotton was handled for which the handler is required to collect assessments during the reporting period. A collecting handler who handles cotton only during certain months shall file a final no cotton purchased report at the conclusion of such handler's marketing season. If a collecting handler handles cotton during any month following submission of the final report for the handler's marketing season, such handler shall send a collecting handler report and remittance to the Cotton Board by the 10th day of the month following the month in which cotton was handled. The no cotton purchased report shall be signed and dated by the handler or the handler's agent.

(3) *Remittances.* The collecting handler shall remit all assessments to the Cotton Board with the report required in paragraph (a)(2) of this section. All remittances sent to the Cotton Board by collecting handlers shall be made by check, draft, or money order payable to the order of the "Cotton Board". All remittances shall be received subject to collection and payment at par.

(4) *Interest and Late Payment Charges.* (i) There shall be an interest charge, at rates prescribed by the Cotton Board with the approval of the Secretary, on any handler who is sent a second certified mail notice of past-due assessments from the Cotton Board in any one marketing year (August 1–July 31).

(ii) In addition to the interest charge specified in paragraph (a)(4)(i) of this section, there shall be a late payment charge on any handler whose remittance is not received by the Cotton Board within 10 days after the close of the reporting period in which interest charges were first accrued. The late payment shall be 5 percent of the unpaid balance before interest charges have accrued.

(iii) The interest and late payment charges on the unremitted assessments for a particular reporting period will be applied from the first working day on or following the 20th day of the month in which the assessments were due.

(b) *Importer Reports and Remittance.* The United States Customs Service will transmit reports and assessments collected on imported cotton to the Agricultural Marketing Service according to the agreement between the Customs Service and the Agricultural Marketing Service. Upon the request of the Cotton Board, an importer shall file with the Board a report, for a period of time specified in the request, that includes the following information:

(1) The importer's name and address;

(2) The quantity of cotton and cotton products imported;

(3) The amount of the assessment paid on imported cotton and cotton products;

(4) The amount of imported cotton and cotton products on which the assessment was not paid to the Customs Service.

11. Section 1205.515 "Failure to report and remit" is redesignated as § 1205.517 and revised to read as follows.

§ 1205.517 Failure to report and remit.

(a) Any collecting handler who fails to submit reports and remittances according to reporting periods and time schedules required in § 1205.516 shall be subject to appropriate action by the Cotton Board which may include one or more of the following actions:

(1) Audits of the collecting handler's books and records to determine the amount owed the Cotton Board;

(2) Requirement that an escrow account for the deposit of assessments collected be established. Frequency and schedule of deposits and withdrawals from the escrow account shall be determined by the Cotton Board with the approval of the Secretary;

(3) Referral to the Secretary for appropriate enforcement action;

(4) Publication of a collecting handler's name in accordance with the following provisions:

(i) The name of any collecting handler will be subject to publication if the collecting handler:

(A) Is sent two certified mail notices of past due assessments and/or collecting handler reports from the Cotton Board in any one marketing year (August 1–July 31), or

(B) Is required by the Cotton Board to establish an escrow account for depositing assessments, in accordance with paragraph (a)(2) of this section, and does not comply with the deposit procedures established by the Cotton Board with approval of the Secretary.

(ii) The name of any collecting handler who is subject to publication will be published by the Cotton Board with the approval of the Secretary in a monthly listing during the primary cotton marketing season (September through March) and a bimonthly listing during the remainder of the year. The published listing will be distributed by the Cotton Board.

(iii) The Cotton Board, with approval of the Secretary, may notify individual producers that the assessments collected by such producer's collecting handler, whose name is subject to publication in accordance with the provisions of paragraph (a)(4)(i) of this section, have not been remitted to the Cotton Board as required.

(b) Any importer who fails to submit,

(1) Reports to the Cotton Board pursuant to request made according to § 1205.516 or

(2) Assessments to the Customs Service, shall be subject to one or more of the following actions:

(i) Audits of the importer's books and records to determine the amount owed the Cotton Board.

(ii) A deduction for the amount of any unpaid assessment by the Customs Service from the importers surety bond.

(iii) Referral to the Secretary for appropriate enforcement action.

12. Section 1205.514 "Customs Service and the collection of the $1 per bale assessment" is added to read as follows:

§ 1205.514 Customs Service and the Collection of the $1 per bale assessment.

Customs Service and the Collection of the $1 per bale assessment shall be as follows:

(a) The Customs Service will collect the assessment from the importer or from any person acting as principal, agent, broker or consignee for cotton or cotton-containing products produced outside the United States and imported into the United States. The Customs Service will collect the assessment on cotton and cotton-containing products identified by Harmonized Tariff Schedule heading numbers in § 1205.510(b)(2) at the time of importation and forward such

assessment as per the agreement between the United States Customs Service and the Department of Agriculture.

(b) In the event of an importer's death, bankruptcy, receivership, or incapacity to act, the representative of such importer, or the importer's estate, or the person acting on behalf of creditors, shall be considered the importer for the purposes of this section.

13. Section 1205.515 "Customs Service and collection of the supplemental assessment" is added to read as follows:

§ 1205.515 Customs Service and the collection of the supplemental assessment.

Customs Service and the collection of the supplemental assessment shall be as follows:

(a) The Customs Service will collect the supplemental assessment from any person acting as principal, agent, broker or consignee for cotton or cotton-containing products produced outside the United States and imported into the United States. Customs Service will collect the assessment on all cotton and cotton-containing products identified by Harmonized Tariff Schedule heading numbers in § 1205.510(b)(2) at the time of importation and forward such assessment as per the agreement between the United States Customs Service and the Department of Agriculture.

(b) In the event of an importer's death, bankruptcy, receivership, or incapacity to act, the representative of such importer, or the importer's estate, or the person acting on behalf of creditors, shall be considered the importer for the purposes of this section.

Reimbursements

14. Section 1205.520 "Procedure for obtaining refund" is revised to read as follows:

§ 1205.520 Procedure for obtaining reimbursement.

Each importer against who's imports of cotton or cotton-containing products any assessments are made and collected may obtain a reimbursement on that portion of the assessment that was collected on cotton produced in the United States or cotton other than Upland cotton only by following the procedures prescribed in this section.

(a) *Application form.* An importer shall obtain a reimbursement application form from the Cotton Board. Such form may be obtained by written request to the Cotton Board and the request shall bear the importer's signature or the importer's properly-witnessed mark.

(b) *Submission of Reimbursement Application to Cotton Board.* Any importer requesting a reimbursement shall mail the application on the prescribed form to the Cotton Board. The application shall be postmarked within 90 days from the date the assessments were paid on the cotton by such importer. The reimbursement application shall show.

(1) The importer's name, address, phone number and Customs Service identification number;

(2) Weight of the cotton in each HTS category for which the reimbursement is requested;

(3) Subtotal amounts to be reimbursed for each HTS number and grand total to be reimbursed;

(4) Date or inclusive dates on which the assessments were paid;

(5) The name of the port of entry; and

(6) Certification by the importer that the cotton was grown in the U.S. or is other than Upland cotton.

(c) Where more than one importer shared in the assessment payment on cotton joint or separate reimbursement application forms may be filed. In any such case, the reimbursement application shall show the names, addresses and proportionate shares of assessments paid by all importers. The reimbursement application shall bear the signature of each importer seeking reimbursement.

(d) *Proof of payment of the assessment on U.S. produced or other than Upland cotton.* A copy of the Customs entry form and the commercial invoice filed with the Customs Service shall accompany the importer's reimbursement application. Within 60 days from the date the properly executed application for reimbursement is received by the Cotton Board, the Cotton Board shall make reimbursement to the importer. For joint applications, the reimbursement shall be made payable to all eligible importers signing the reimbursement application. Documentation submitted with reimbursement applications shall not be returned to the importer.

Warehouse Receipts

15. Section 1205.525 "Entry of gin code number" is revised to read as follows:

§ 1205.525 Entry of gin code number.

The warehouse that first receives a bale for storage after ginning shall enter the gin code number of the gin at which the bale was ginned on the warehouse receipt issued for the bale.

Reports and Records

16. Section 1205.530 "Gin reports and reporting schedule" is amended by revising paragraph (a)(2) to read as follows:

§ 1205.530 Gin reports and reporting schedule.

(a) * * *

(2) *Certificate in Lieu of End-of-Season Report.* If a gin is the collecting handler on every bale ginned at such gin and collecting handler reports and remittances of assessments have been made in accordance with § 1205.516, a certification to that effect may be made to the Cotton Board in lieu of an end-of-season report.

* * * * *

17. Section 1205.531 "Records" is revised to read as follows:

§ 1205.531 Records.

Each handler or importer required to make reports pursuant to this subpart shall maintain such books and records as are necessary to verify the reports.

18. Section 1205.532 "Retention period for reports and records" is revised to read as follows:

§ 1205.532 Retention period for reports and records.

Each handler and importer required to make reports pursuant to this subpart shall retain for at least 2 years beyond the marketing year of their applicability:

(a) One copy of the report made to the Cotton Board; and

(b) Such books and records as are necessary to verify such reports.

19. Section 1205.533 "Availability of Reports and Records" is revised to read as follows:

§ 1205.533 Availability of reports and records.

Each handler and importer required to make reports pursuant to this subpart shall make available for inspection by the Cotton Board, including its designated employees, and the Secretary any reports, books, or records required under this subpart.

Confidential Information

20. Section 1205.540 "Confidential Books, Records, and Reports" is revised to read as follows:

§ 1205.540 Confidential books, records, and reports.

All information obtained from the books, records, and reports of handlers and importers shall be kept confidential in the manner and to the extent provided for in § 1205.340 of this part.

Dated: December 6, 1991.

Jo Ann R. Smith,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 91-30001 Filed 12-16-91; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[GL-174-89]

RIN 1545-AN47

Sale of Seized Property; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of public hearing on proposed Income Tax Regulation that relates to the request for the sale of seized property under section 6335(f) of the Internal Revenue Code of 1986.

DATES: The public hearing originally scheduled for Tuesday, December 17, 1991, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Felicia A. Daniels of the Regulations Unit, Assistant Chief Counsel (corporate), 202-566-3935 (not toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 6335(f) of the Internal Revenue Code of 1986. A notice of public hearing appearing in the **Federal Register** for Wednesday, October 9, 1991 (56 FR 50833), announced that the public hearing on the proposed regulations would be held on December 17, 1991, beginning at 10 a.m. in the Internal Revenue Service Building, second floor, room 2615, 1111 Constitution Avenue, NW., Washington, DC 20224.

The public hearing scheduled for Tuesday, December 17, 1991, has been cancelled.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 91-30185 Filed 12-13-91; 12:40 pm]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80 and 86

[FRL-4083-7]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines: Evaporative Emission Regulations for Gasoline- and Methanol-Fueled Light-Duty Vehicles and Light-Duty Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public workshop and report availability.

SUMMARY: This notice announces the availability of a new technical report and the time and place for a public workshop related to EPA's proposed evaporative emission control regulations. In addition, draft regulations and draft supporting analyses related to the test procedures are available for public review. This notice seeks comment, both oral and written, on the report, regulations, and supporting analyses.

DATES: The public workshop will be held on January 8, 1992. It will start at 9 a.m. and will continue throughout the day as long as necessary to complete testimony. Comments will be accepted until January 22, 1992.

ADDRESSES: The public workshop will be at Activities Hall, Domino's Farms, 24 Frank Lloyd Wright Dr., Ann Arbor, Michigan 48105 (telephone 313-930-5032). Interested parties may submit written comments (in duplicate if possible) to Public Docket No. A-89-18, at: Air Docket Section (LE-131), U.S. Environmental Protection Agency, Attention: Docket No. A-89-18, First Floor, Waterside Mall, rm. M-1500, 401 M Street, SW., Washington, DC 20460.

Materials related to this rulemaking have been placed in Docket A-89-18 by EPA. The docket is located at the above address and may be inspected between 8:30 a.m. and noon and between 1:30 p.m. and 3:30 p.m., Monday through Friday. EPA may charge a reasonable fee for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Stout, Standards Development and Support Branch, Emission Control Technology Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105. Telephone: (313) 741-7805.

For copies of support documents, contact: Ms. Margaret Borushko, (313) 668-4272.

SUPPLEMENTARY INFORMATION: On January 19, 1990 EPA published a Notice of Proposed Rulemaking (NPRM) detailing a revised procedure to test vehicles for evaporative emissions (55 FR 1914). The test included an initial step to load the evaporative canister to breakthrough, then the exhaust emission test, followed by repeated high-temperature diurnal heat builds. The test also included provisions to ensure that vehicles could control running losses. The NPRM also requested comment on an alternative "real time" test concept advanced by General Motors (GM).

In response to the comments received following the January 1990 NPRM, EPA subsequently held a public workshop to provide further opportunity for comment on several possible modifications to the proposed test procedure. These modifications included the addition of running loss and resting loss tests to the end of the procedure, as well as various adjustments to the method of testing. The workshop also provided an additional opportunity for comment on the GM real time test.

More recently, EPA has completed a draft analysis related to the GM real time test which supports a revised sequencing of test segments of the GM test ("Emission Evaluation of the GM Real Time Evaporative Test Procedure"). The necessary revision to the GM sequence makes it consistent with the sequence presented and commented on at the December 1990 public workshop. Because of the importance of this issue, the Agency has decided once again to open the rulemaking record and hold an additional public workshop for the purpose of presenting and receiving comment on its analysis.

EPA is also providing the public the opportunity to review staff positions on several other issues, each of which has been commented on previously. These staff positions are discussed in a technical report, entitled "Supplementary Information—EPA Proposal for Control of Evaporative Emissions." Also, EPA staff have drafted more detailed regulations for the test procedure options. All these documents are available for public inspection in the public docket (see "ADDRESSES" above). One outcome of EPA's rulemaking could be that EPA would adopt test procedures, such as described in the draft regulations, which are different from those adopted by CARB. EPA requests comment on such an outcome, and ways to minimize its impact if it occurred.

Public Participation

As in past rulemaking actions, EPA strongly encourages full public participation in the development and assessment of information that will be used in developing a final rule. In particular, comment is invited on the draft analysis and other supporting information identified above. For those submitting comments, whenever possible, full supporting rationale, data, and detailed analyses should be submitted to allow EPA to make maximum use of the comments.

EPA will make a presentation highlighting its sequencing analysis and some other key portions of the rulemaking. After EPA's presentation, attendees will be encouraged to ask questions and make oral presentations. Any person desiring to present testimony at the public workshop should notify the contact person listed above of such intent at least seven days before the workshop. The contact person also should be provided an estimate of the time required for the presentation of the testimony and notification of any need for audio/visual equipment. A sign-up sheet will be available at the registration table the morning of the workshop to schedule the order of testimony.

EPA suggests that enough copies of the statement or material for presentation be brought to the workshop for distribution to the audience. In addition, it will be helpful for EPA to receive an advance copy of any statement or material for presentation before the scheduled workshop date, for EPA staff to give such material full consideration. The official record of the workshop will be kept open for 14 days following the workshop to allow submission of rebuttal and supplementary testimony.

Mr. Richard D. Wilson, Director of the Office of Mobile Sources, will be the presiding officer of the workshop. The workshop will be conducted informally, and technical rules of evidence will not apply. A court reporter will be present at the workshop to make a transcript of the proceedings and a copy will be placed in the docket. Anyone desiring a copy of the transcript should make individual arrangements with the court reporter at the time of the workshop.

Dated: December 10, 1991.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 91-30086 Filed 12-16-91; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 300

[FRL-4037-5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of Intent to Delete Westline Site from the National Priorities List: Request for Comments.

SUMMARY: The Environmental Protection Agency (EPA) Region III announces its intent to delete the Westline Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendment and Reauthorization Act of 1986, Public Law Number 99-499 (CERCLA), as amended 42 U.S.C. Section 9605 EPA and the Commonwealth of Pennsylvania have determined that all appropriate CERCLA actions have been implemented and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the Commonwealth have determined that remedial activities conducted at the Site to date have been protective of public health, welfare, and the environment.

DATES: Comments concerning this Site may be submitted on or before January 16, 1992.

ADDRESSES: Comments may be mailed to Roy Schrock, Remedial Project Manager, Superfund Branch, (3HW22), Environmental Protection Agency, 841 Chestnut Street, Philadelphia, PA 19107.

Comprehensive Information on this Site is available through the Region III public docket which is available for viewing at the Westline Site information repositories at the following locations:

McKean County Courthouse, McKean County Planning Office, Main Street, Smethport, PA 16749

Bradford Area Public Library, 27 Congress or 67 West Washington, Bradford, PA 16701

Westline Firehall, Westline, PA 16751

FOR FURTHER INFORMATION CONTACT: Roy Schrock, U.S. EPA Region 3, 841 Chestnut Street, Philadelphia, PA 19107, (215) 597-0913.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Intended Site Deletion

I. Introduction

The Environmental Protection Agency (EPA) Region III announces its intent to delete a site from the National Priorities List (NPL), appendix B, of the National Oil and Hazardous Substances Contingency Plan ("NCP"), 40 CFR as amended, and requests comments on this deletion. The EPA identifies sites that appear to present a significant risk to human health or the environment and maintains the NPL as the list of those sites. Sites on the NPL may be remediated using the Hazardous Substances Superfund. As described in § 300.425(e)(3) of the NCP, any sites deleted from the NPL remain eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action.

EPA plans to delete the Westline Site in Lafayette Township, McKean County, Pennsylvania from the NPL.

EPA will accept comments on this Site for thirty days after publication of this notice in the **Federal Register.**

Section II of this notice explains the criteria for deleting sites from the NPL. Section III discusses procedures that the EPA is using for this action. Section IV discusses the Westline Site and explains how the Site meets the deletion criteria.

II. NPL Deletion Criteria

Amendments to the NCP published in the **Federal Register** on March 8, 1990 (55 FR 8666) establish the criteria the Agency uses to delete sites from the NPL. Section 300.425(e) of the NCP, 40 CFR 300.425(e), provides that releases may be deleted from or recategorized on the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Fund-financed response under CERCLA has been implemented, and no further action by responsible parties is appropriate; or

(iii) The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

In addition to the above, for all remedial actions which result in hazardous substances, pollutants, or

contaminants remaining at the site above levels that allow unlimited use and unrestricted exposure, it is EPA's policy that sites generally review has been conducted following completion of all remedial actions at a site (except operations and maintenance), any appropriate actions have been taken to ensure that the site remains protective of public health and the environment, and the site meets EPA's deletion criteria as outlined above.

The Remedial Action implemented at the Westline Site involved excavation of the largest tar lagoon and some of the underground deposits of the tar along the creek. The excavated materials were transported to an offsite incinerator for treatment and disposal. Following the remediation activities, EPA developed a guidance document for risk calculations and the Agency revised the risks associated with the polynuclear aromatic hydrocarbons (PAHs). When the risk calculations were revised it was determined that the contaminants were removed from the Site allowing for unlimited use and unrestricted exposure. Consistent with OSWER Directive 9355.7–02, a five-year review is not necessary at the Westline Site because hazardous materials remaining on site allow for unlimited use and unrestricted exposure.

III. Deletion Procedures

In the NPL rulemaking published on October 15, 1984 (49 FR 40320), the Agency solicited and received comments on whether the notice of comment procedures followed for adding sites to the NPL should also be used before sites are deleted. Comments were also received in response to the amendments to the NCP proposed on December 21, 1988 (53 FR 51394).

The following procedures were used for the intended deletion of this Site: (1) That EPA Region III has prepared the relevant documents, (2) the Commonwealth of Pennsylvania has concurred with the deletion decision, (3) a notice has been published in local newspapers and has been distributed to appropriate Federal, state and local officials, and other interested parties, and the starting date of the 30-day public comment period, and (4) all relevant documents have been made available in the local site information repositories.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual rights or obligations. The NPL is designed primarily for information purposes and to assist Agency management. As mentioned in section II of this Notice, 40 CFR 300.425(e)(3) states that deletion of a site from the NPL does not preclude eligibility for future Fund-financed response actions.

For deletion of this site, EPA's Regional Office will accept and evaluate public comments before making the final decision to delete.

A deletion occurs when the Regional Administrator places a notice in the **Federal Register**. Generally the NPL will reflect deletions in the final update following the Notice. Public notices and copies of the Responsiveness Summary will be made available to local residents by the Regional Office.

IV. Basis for Intended Site Deletion

The following site summary provides the Agency's rationale for the intention to delete this site from the NPL.

Westline Site, Lafayette Township, McKean County, Pennsylvania

The Westline Site is located in the rural town of Westline, McKean County, Pennsylvania. The town is situated along Kinzua Creek and is completely surrounded by the Allegheny National Forest. Approximately 100 people reside in the town Westline at present.

During the period from 1901 to 1952 a chemical company operated in Westline converting wood into charcoal, methanol and acetic acid. A tar-like waste was generated by the chemical process and deposited onto the ground, eventually forming several lagoons. Chemical analysis of the tar reveals phenol, 2,4-dimethylphenol and polynuclear aromatic hydrocarbons (PAHs). Today, all that is left of the chemical plant is the foundation. The office of the former plant is now a restaurant and bar, which has been named the Westline Inn.

The Site Inspection (SI) occurred in 1982 and the Site was listed on the NPL in 1983. In February of 1983 EPA Region III began an immediate removal action at the Site. In April 1983 the largest lagoon of tar deposits, located in the parking lot of the Westline Inn, was capped to prevent offsite migration. By August, 1983 it became apparent that the clay cap was inadequate and excavation and removal of the tar material was necessary. Variations in temperature and the water table level caused the tar to seep out from under the capped area. Therefore, excavation began in August, 1983. Two thousand tons of tar and contaminated soil were removed from the Site by CECOS International, Inc. and taken to CECOS' disposal Site in Niagara Falls, New York. The removal action was completed on or about September 14, 1983.

The remedial action began in March of 1983 when a work assignment was issued to NUS Corporation. NUS prepared a Remedial Action Master Plan (RAMP) in October 1983. The RAMP summarized all previous information. By August of 1984, NUS prepared a work plan for the remedial Investigation/Feasibility Study (RI/FS). NUS installed monitoring wells and collected groundwater samples from the monitoring wells and from several residential wells. They collected surface water and sediment samples from Kinzua Creek and from the small tributaries on the Site. They collected fish samples and benthic organism from the creek. They also collected soil samples from the surface and subsurface areas throughout the Site.

The results of this sampling effort revealed two areas where health risks were of concern. The waste tar on Site contained phenols and PAHs at levels which could cause a direct contact threat to the residents in the town of Westline, particularly small children who might come into contact with the larger lagoons on the Site. The other concern was found in groundwater. In one of the monitoring wells behind the Westline Inn, possibly gasoline-related compounds were found which did not seem to be directly related to the tar like materials that caused the Site to be listed on the NPL. Specifically, benzene was found at 80 ppb which clearly exceeded the maximum concentration levels (MCL) of 5 ppb.

NUS completed the RI/FS reports by July of 1986 and a Record of Decision (ROD) was signed on July 3, 1986. This ROD called for excavation of the waste tar/soil mixture and for offsite incineration of the materials. The ROD also required a groundwater verification study of the "non tar-related" compounds found during the RI.

The community relations activities conducted during the period of this ROD included the released of the documents used in the decision making process and a public meeting which was held a few weeks prior to the signing of the ROD. Public reaction to the EPA investigation was somewhat surprising. The general attitude was that the tar was not really that much of a problem; the public did not understand why the Agency was spending so much money investigating the tar which has been there for so many years. A majority of the residents did not think that the excavation and offsite incineration were necessary. Some felt, however, that if EPA's actions

would protect the future environment of their town then they could agree with such actions.

The groundwater verification study and the remedial design work assignment for offsite incineration began in the fall of 1986. EBASCO/NUS prepared the work plans and conducted the additional field studies in the summer of 1987. The groundwater verification study report was issued in December of 1987 and a second ROD was signed on June 29, 1988. The groundwater RI showed that benzene was still present in the well behind the Westline Inn and in one other new well installed downgradient from the contaminated well; the concentrations in the well behind the Inn had decreased from 80 ppb to 60 ppb and the new well showed only 9 ppb. The ROD stated that concentrations of benzene were decreasing with time and that the aquifer should flush out the contaminants within five to ten years. Therefore, a No Action Alternative with continued monitoring was selected. The wells are to be monitored for a period of five years.

Another important factor in this decision was that none of the residents were using the groundwater for drinking purposes. The town's water was derived from one of the tributaries to the creek and was collected far up on the hill away from any of the contaminated areas of the Site.

For the second ROD the repositories were updated with the new documents and another public availability session was held. Three of the local newspapers attended and wrote articles in these local newspapers which service the area residents. The public reaction to the second ROD was more positive. The Agency made a decision not to spend more money and the public was in agreement.

To verify the site cleanup action level (70,000 ug/kg for total polynuclear aromatic hydrocarbons), an EPA-owned mobile laboratory was provided at the Westline Site. The onsite analysis was performed using a Gas Chromatographic Flame Ionization Detector (GCFID). Analyses and associated field laboratory QA/QC were accomplished using a modified RCRA Method 8100 analytical protocol. Approximately 10 percent of the samples were shipped to a fixed-base REM III laboratory for analysis to verify the mobile laboratory results.

A total of 133 soil samples were collected and analyzed during the remediation to confirm that the remaining soil met the site action level. The analytical results for these samples are tabulated in the "Final Project Summary Report for Remedial Action at the Westline Site" dated 1989 for both the mobile laboratory and the fixed-based laboratory.

Operation and maintenance (O&M) activities for the excavated areas were limited only to restoration of the surface features. All excavated areas were backfilled with clean soils and revegetated. The area where the tar pit was behind the church is now an open field area and used for gatherings of cross country skiers in the area. The support areas were cleaned up before demobilization, but some additional soil grading and seeding was done the following summer.

In contrast to the excavation activities the groundwater ROD did call for operation and maintenance activities. As discussed earlier the first samples taken in 1985 indicated high levels of benzene and other gasoline compounds. The second samples taken in 1987 indicated a decrease in benzene concentrations and the 1988 ROD predicted the contaminants would be flushed out by normal groundwater movement towards Kinzua creek.

Operation and maintenance samples were collected by the Regional Field Investigation Team in the summer of 1990 and the results were excellent. The benzene was not detected at all in the originally contaminated well behind the Westline Inn. The other well which had 9 ppb in 1987 had decreased to 2 ppb which is within acceptable limits for EPA's MCLs. Therefore the normal flushing out of the contaminants was successful at this Site.

It is expected, however, that the PADER will conduct one more round of sampling within the next two years just to complete these O&M activities. Pennsylvania has signed a Superfund State Contract (SSC) to conduct one more round of monitoring at the site.

Based on the prior excavation of the two largest lagoons at the site and the revised risk assessment, hazardous substances, pollutants and contaminants were removed from the Site allowing for unlimited use and unrestricted exposure within the Site.

Dated: September 18, 1991.

William T. Wisniewski,

Acting Regional Administrator, Region III.

[FR Doc. 91-30087 Filed 12-16-91; 8:45 am]
BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 63

[CC Docket No. 87-266; FCC 91-334]

Facilities for the Provision of Video Programming by a Telephone Common Carrier in its Telephone Service Area

AGENCY: Federal Communications Commission (FCC).

ACTION: Proposed rule.

SUMMARY: The Commission requests comment on its proposed rule changes and regulatory policy with respect to video dialtone. The Commission proposed alternative regulatory approaches to video dialtone for local exchange carriers and tentatively concluded that the approach that best serves the public interest would consist of video dialtone provided on two levels. The first level would consist of Title II basic regulated services. The second level would consist of enhanced and other non-Title II services subject to competition among service providers. The proposed video dialtone policy will promote the Commission's goals of development of an advanced communications infrastructure, free and open competition and a diversity of information sources.

DATES: Comments must be filed by January 23, 1992. Reply comments are due by February 24, 1992.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Donna Lampert, Common Carrier Bureau, (202) 632-6363 or Greg Lipscomb, Common Carrier Bureau, (202) 634-1800.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The proposals contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980, as amended, 44 U.S.C. 3501-3520, and found to impose no new or modified form, information collection and/or recordkeeping, labeling, disclosure or record retention requirements; and will not increase burden hours imposed on the public. Implementation of any new or modified requirement will be subject to approval by the Office of Management and Budget as prescribed by that Act.

Background

Common Carrier Docket 87-266: Telephone Company/Cable Television

Cross Ownership Rules, §§ 63.54–63.58, Notice of Inquiry, 2 FCC Rcd 5092 (1987) (52 FR 34818 (9/15/87)); Telephone Company/Cable Television Cross Ownership Rules, §§ 63.54–63.58, Further Notice of Inquiry and Notice of Proposed Rulemaking, 3 FCC Rcd 5849 (1988) (53 FR 38042 (9/29/88)).

Summary of Further Notice of Proposed Rulemaking and Second Further Notice of Inquiry

This is a summary of the Commission's Further Notice of Proposed Rulemaking and Second Notice of Inquiry relating to Common Carrier Docket 87–266: Telephone Company/Cable Television Cross Ownership Rules, §§ 63.54–63.58, Adopted: October 24, 1991 and Released: November 22, 1991. The full texts of Commission decisions are available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC 20554. The complete text of this Further Notice of Proposed Rulemaking and Second Further Notice of Inquiry may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1114 21st Street, NW., Washington, DC 20036.

In the Further Notice of Proposed Rulemaking, the Commission has proposed rule change in connection with its tentative regulatory policy for video dialtone. The Commission tentatively concluded that a video dialtone policy will provide the best foundation to achieve the goals of promoting the development of an efficient, nationwide, publicly accessible, advanced telecommunications infrastructure, facilitating robust competition, and fostering the First Amendment goal of ensuring a diversity of information sources. The Commission proposed that video dialtone be common carrier-based with the addition of competitive non-common carrier services that would provide end users access to video programming and other information sources.

The Commission proposed alternative regulatory approaches to video dialtone for local exchange carriers and seeks comment on other approaches. The Commission has tentatively concluded that the approach that best serves the public interest would consist of video dialtone provided on two levels. The first level would consist of Title II basic regulated services and would provide an "electronic platform" or "window" that opens to a broader network, giving end users access to video and non-video communication services provided by a multiplicity of competitive service providers. The second level would consist of enhanced and other non-Title II services subject to competition among service providers. The proposed video dialtone policy will promote the Commission's goals of development of an advanced communications infrastructure, free and open competition and a diversity of information sources.

In the Second Further Notice of Inquiry, the Commission seeks comment on the risks and benefits of permitting local exchange carriers to provide video programming directly to consumers in the video dialtone context and asks whether any changes in the statutory ban should be recommended to Congress. Comment is also requested on whether current regulatory incentives support the stated video dialtone policy.

Ordering Clauses

It is ordered that, pursuant to sections 1, 4, 201–205, 218, 220, 303(r) and 403 of the Communications Act of 1934, as amended, and section 601 of the Cable Communications Policy Act of 1984, as amended, 47 U.S.C. 151, 154, 201–205, 218, 220, 303(r), 403 and 521; and 5 U.S.C. 553, a second further notice of inquiry is hereby provided as explained herein.

It is further ordered that, pursuant to sections 1, 4, 201–205, 215, 218, 220, 303(r) of the Communications Act of 1934, as amended, and sections 601, 612 and 613 of the Cable Communications Policy Act of 1984, as amended, 47 U.S.C. 151, 154, 201–205, 215, 218, 220, 303(r), 521, 532 and 533; and 5 U.S.C. 553, further notice of proposed rulemaking is hereby provided to amend § 63.54 of the Commission's rules, 47 CFR 63.54, as indicated herein.

It is further ordered that, the Secretary shall send a copy of this Further Notice of Proposed Rulemaking, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act. Public Law No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

List of Subjects in 47 CFR Part 63

Cable television, Communications Common Carriers, Telephone, Video dialtone.

Proposed Rule Changes

It is proposed that Part 63 of Title 47 of the Code of Federal Regulations be amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: Sec. 4, 48 Stat. 1066, as amended 47 U.S.C. 154. Interpret or apply sec. 214, 48 Stat. 1075, as amended; 47 U.S.C. 214.

2. Section 63.54 is amended by adding paragraph (c) to Note 1 to read as follows:

§ 63.54 Facilities for provision of video programming by a telephone common carrier in its telephone service area.

* * * * *

Note 1: * * * (c) Nothing in this section shall be construed to prohibit the provision of video dialtone services, enhanced services related to video dialtone, advanced video gateways and other related non-programming video dialtone functions by a telephone common carrier.

* * * * *

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91–30047 Filed 12–16–91; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 56, No. 242
Tuesday, December 17, 1991

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

[A-588-819]

Postponement of Final Antidumping Duty Determination: Aspheric Ophthalmoscopy Lenses From Japan

AGENCY: Import Administration, International Trade Administration, Commerce.

EFFECTIVE DATE: December 17, 1991.

FOR FURTHER INFORMATION CONTACT: Stefanie Amadeo, Office of Antidumping Duty Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230, at (202) 377-1174.

Postponement: This notice informs the public that we have received a request from Nikon Corporation and Nikon, Inc. ("Nikon"), respondent in this investigation, to postpone the final determination until not later than 135 days after the date of the publication of the preliminary determination in the investigation of aspheric ophthalmoscopy lenses (lenses) from Japan, in accordance with section 735(a)(2)(A) of the Tariff Act of 1930, as amended (the Act) (19 U.S.C. 1673d(a)(2)). Nikon accounts for a significant proportion of exports of the subject merchandise from Japan to the United States. Pursuant to 19 CFR 353.20(b), if exporters who account for a significant proportion of exports of the merchandise under investigation request an extension subsequent to an affirmative preliminary determination, we are required, absent any compelling reasons to the contrary, to grant the request. Accordingly, we are postponing the date of the final determination as to whether sales of lenses from Japan have occurred at less than fair value until not later than February 21, 1992.

Public comment: Because no interested parties have requested a hearing we have not scheduled one. In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary no later than December 16, 1991, and rebuttal briefs no later than December 20, 1991.

The U.S. International Trade Commission is being advised of this postponement, in accordance with section 735(d) of the Act.

This notice is published pursuant to section 735(d) of the Act and 19 CFR 353.20(b)(2).

Dated: December 12, 1991.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 91-30090 Filed 12-16-91; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration

Massachusetts Institute of Technology, et al.; Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in room 4204, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Comment: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

Docket Number: 90-218R. *Applicant:* Massachusetts Institute of Technology, Cambridge, MA 02139. *Instrument:* Isotope Mass Spectrometer, Model 215-50. *Manufacturer:* Mass Analyser Products Ltd., United Kingdom. *Intended Use:* See notice at 56 FR 1512, January 15, 1991. *Reasons:* The foreign instrument provides a sensitivity of $6.0x10^{-4}$ A/torr for M/e 40 and an M/e 36 background less than $5.0x10^{-14}$ cm^3 STP.

Docket Number: 90-222R. *Applicant:* University of Southern California, Los Angeles, CA 90089-0740. *Instrument:* Mass Spectrometer, Model VG PRISM. *Manufacturer:* VG Instruments Incorporated, United Kingdom. *Intended Use:* See notice at 56 FR 1512, January 15, 1991. *Reasons:* The foreign instrument provides an internal precision of 0.006 per mil for 3 bar μl samples of Co_2 and an integrated carbonate sample preparation system.

Docket Number: 91-109. *Applicant:* Michigan State University, East Lansing, MI 48824-1115. *Instrument:* Mass Spectrometer, Model PRISM Series II. *Manufacturer:* VG Isotech, United Kingdom. *Intended Use:* See notice at 56 FR 41120, August 19, 1991. *Reasons:* The foreign instrument provides a precision of 0.006 per mil for 3 bar μl samples of CO_2.

The capability of each of the foreign instruments described above is pertinent to each applicant's intended purposes. We know of no instrument or apparatus being manufactured in the United States which is of equivalent scientific value to either of the foreign instruments.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 91-30091 Filed 12-16-91; 8:45 am]

BILLING CODE 3510-DS-M

Veterans Administration Medical Center, et al.; Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in room 4204, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 91-134. *Applicant:* Veterans Administration Medical Center, Washington, DC 20422. *Instrument:* Electron Microscope, Model CM 10. *Manufacturer:* N.V. Philips, The Netherlands. *Intended Use:* See notice at 56 FR 47188, September 18, 1991. *Order Date:* April 30, 1991.

Docket Number: 91-136. *Applicant:* The University of Toledo, Toledo, OH 43606. *Instrument:* Electron Microscope, Model EM 902/PC. *Manufacturer:* Carl Zeiss, West Germany. *Intended Use:* See

notice at 56 FR 50096, October 3, 1991. *Order Date:* April 30, 1991.

Docket Number: 91–145. *Applicant:* Veterans Administration Medical Center, Durham, NC 27705. *Instrument:* Electron Microscope, Model JEM–1200EX. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* See notice at 56 FR 56408, November 4, 1991. *Order Date:* August 16, 1991.

Docket Number: 91–147. *Applicant:* The Ohio State University, Columbus, OH 43210. *Instrument:* Electron Microscope, Model EM 900 PC. *Manufacturer:* Carl Zeiss, West Germany. *Intended Use:* See notice at 56 FR 56408, November 8, 1991. *Order Date:* July 2, 1991.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered. *Reasons:* Each foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of each instrument or at the time of receipt of application by the U.S. Customs Service.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 91–30092 Filed 12–16–91; 8:45 am]

BILLING CODE 3510–DS–M

Wright State University, et al.; Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in room 4204, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

Docket Number: 90–213R. *Applicant:* Wright State University, Dayton, OH 45435. *Instrument:* Gas Chromatograph Mass Spectrometer System, Model MS 890. *Manufacturer:* Kratos Analytical Inc., United Kingdom. *Intended Use:* See notice at 55 FR 51752, December 17, 1990. *Reasons:* The foreign instrument provides femtogram sensitivity for dioxin (PCDD and PCDF) and rapid switching software for selected ion monitoring at resolution of 10 000. *Advice Submitted By:* National Institutes of Health, November 5, 1991.

Docket Number: 91–111. *Applicant:* University of Washington, Seattle, WA 98195. *Instrument:* Mass Spectrometer, Model Profile HV–3. *Manufacturer:* Kratos Analytical Inc., United Kingdom. *Intended Use:* See notice at 56 FR 41120, August 19, 1991. *Reasons:* The foreign instrument provides: (1) A liquid chromatograph particle beam interface, (2) scan speeds to 0.1 second per decade and (3) continuous flow FAB. *Advice Submitted By:* National Institutes of Health, November 5, 1991.

Docket Number: 91–131. *Applicant:* University of Wisconsin-Madison, Stoughton, WI 53589–3097. *Instrument:* Semiconductor Stepper/Aligner System, Model XRS–200. *Manufacturer:* Karl Suss, West Germany. *Intended Use:* See notice at 56 FR 50095, October 3, 1991. *Reasons:* The foreign instrument provides precise gap control and sub 0.5 μm alignment capability for development of microcircuit lithography. *Advice Received From:* National Institute of Standards and Technology, November 14, 1991.

The National Institutes of Health and National Institute of Standards and Technology advise that (1) the capabilities of each of the foreign instruments described above are pertinent to each applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

We know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to any of the foreign instruments.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 91–30093 Filed 12–16–91; 8:45 am]

BILLING CODE 3510–DS–M

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Amended Export Trade Certificate of Review, Application No. 88–4A017.

SUMMARY: The Department of Commerce has issued an amendment to the Export Trade Certificate of Review granted to the Construction Industry Manufacturers Association ("CIMA") on May 26, 1989. Notice of issuance of the Certificate was published in the **Federal Register** on June 12, 1989 (54 FR 24932).

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202–377–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing title III are found at 15 CFR part 325 (1990) (50 FR 1804, January 11, 1985).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Amended Certificate

Export Trade Certificate of Review No. 88–00017 was issued to the Construction Industry Manufacturers Association ("CIMA") on May 26, 1989 (54 FR 24932, June 12, 1989) and previously amended on April 4, 1990 (55 FR 14100, April 16, 1990), and January 3, 1991 (56 FR 843, January 9, 1991).

CIMA's Export Trade Certificate of Review has been amended to:

1. Add Sioux Steam Cleaner Corporation of Beresford, South Dakota as a "Member" within the meaning of Section 325.2(1) of the Regulations (15 CFR 325.2 (1));

2. Add (a) General Industrial Machinery and Equipment, Not Elsewhere Classified (SIC code 3569) and (b) Service Industry Machinery, Not Elsewhere Classified (SIC code 3589) as products to be covered by the Certificate; and

3. Delete CMI Corporation as a "Member" of the Certificate.

A copy of the amended Certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Dated: December 11, 1991

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 91-30036 Filed 12-16-91; 8:45 am]

BILLING CODE 3510-DR-M

National Technical Information Service

Government-Owned Inventions; Availability for Licensing

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patents are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

Licensing information may be obtained by writing to: National Technical Information Service, Center for Utilization of Federal Technology—Patent Licensing, U.S. Department of Commerce, P.O. Box 1423, Springfield, Virginia 22151 or by telephoning (703) 487–4732. All patent applications may be purchased, specifying the serial number listed below, by writing NTIS, 5285 Port Royal Road, Springfield, Virginia 22161 or by telephoning the NTIS Sales Desk at (703) 487–4650. Issued patents may be obtained from the Commissioner of Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

Please cite the number and title of inventions of interest.

Douglas J. Campion,

Patent Licensing Specialist, Center for the Utilization of Federal Technology.

Department of Health and Human Services

7–189,164 Process for Producing a Human Neutrophil Chemotactic Factor Polypeptide and a Recombinant Expression Vector for the said Polypeptide

7–234,092 (U.S. 5,055,267) Thin Film Environmental Monitor

7–350,908 (U.S. 5,040,539) Pulse Oximeter for Diagnosis of Dental Pulp Pathology

7–352,313 (U.S. 5,063,206) Compositions Having Use as Treatment of Psoriasis and Neurosychiatric Deficits

7–362,357 (U.S. 5,051,557) Microwave Induced Plasma Torch with Tantalum Injector Probe (An An Ion Source for Mass Spectrometry)

7–493,538 (U.S. 5,050,616) Universal Collector for Submandibular-Sublingual Saliva

7–528,080 (U.S. 5,044,363) Waste Gas Released During Surgical Activity (Adsorption System for Scavenging Anesthetic Agents)

7–533,442 (U.S. 5,061,488) Flavone-8-Acetic Acid and Interleukin-2 For Cancer Therapy (especially renal carcinoma)

7–585,793 Complexes of Nitric Oxide With Polyamines

7–620,939 Recombinant Immunotoxin Composed of a Single Chain Antibody Reacting With the Human Transferrin Receptor and Diptheria Toxin

7–623,826 Inhibition of Human Immunodeficiency Virus by an Adeno-associated Virus Gene in Human Cells

7–631,349 A Sensitive Method for Measurement of Chimeric Transcripts of DNA Containing Translocations and Predicting Clinical Course of Disease Related Thereto (Use of Reverse Transcription and PCR to Measure Chimeric mRNA for Monitoring Cancers

7–640,694 Liposome-Incorporation of Polyenes

7–663,455 Recombinant Chimeric Proteins Deliverable Across Cellular Membranes Into Cytosol of Target Cells

7–668,309 Detection of the Common Cystic Fibrosis Mutation (and Similar Small Insertions or Deletions for Detecting Other Genetic Diseases

7–669,090 Monoclonal Antibodies to Cytochrome B5

7–669,731 Modified RNA Template-Specific Polymerase Chain Reaction

7–672,577 The Use of Hydroxamic Acid Derivatives to Inhibit Viral Replication

7–676,174 Octopamine Receptor

7–681,679 Inhibitors of Protein Kinase C Function

7–683,432 Lipophilic, Aminohydrolase-Activated Prodrugs

7–683,440 PCR Induced (Ligase-free) Subcloning: a Rapid and Versatile Method of Subcloning Polymerase Chain Reaction (PCR) Products

7–683,685 A Screening Test That Identifies Individuals At Increased Risk for the Development of Lymphoid Leukemia and Lymphoma

7–688,087 Activity-Dependent Neurothropic Factor

7–690,841 Monoclonal Antibodies Specific for Human Thymidylate Synthase

7–692,923 A Method for Identifying an Individual Homozygous or Heterozygrous for Lactate Dehydrogenase-A Deficiency

7–694,302 Monoclonal Antibodies for Detection of Friend Murine Leukemia Virus

7–696,923 Method for Designing Cancer Treatment Regimens and Methods and Pharmaceutical Compositions for the Treatment of Cancer

7–699,466 A Solid Phase Assay for Proteases

7–707,501 Three Highly Informative Microsatellite Repeat Polymorphic DNA Markers

7–707,502 Human Lactoferrin

7–707,543 Use of Visible Light for Treatment of Immunodeficiency

7–710,180 Transfected Mammalian Cell Lines Expressing the A1 Adenosine Factor

7–710,428 XX174 Transgenic Animals (Useful for Inexpensive Mutagenesis Studies)

7–715,652 Azo Dye Derivatives Exhibiting Anti-HIV Activity, Pharmaceutical Compositions Containing the Same and Methods for Using the Same

7–716,827 Super Glucocorticoid Receptors

7–718,666 Fiber Optic Devices

7–720,174 Osteogenic Composite Implants

7–721,784 Method and Device for Reversible Sterilization

7–732,021 Apparatus for Fluorescent Excitation and Detection from Potentiometric Dyes with a Single-Ended Optical Fiber

7–737,872 System and Method for Performing Simultaneous Bilateral Measurements on a Subject in Motion

7–743,518 Papua New Guinea Human T-Lymphotropic Virus

7–749,240 Stopcock Holder

7–751,090 Interleukin-2 Stimulated T Lymphocyte Cell Death for the Treatment of Autoimmune Diseases, Allergic Disorders, and Graft Rejection

Department of Commerce

7–414,213 (U.S. 5,039,872) Digitally Synthesized Audio Frequency Voltage Source

Department of the Interior

7–367,646 (U.S. 5,043,119) High Strength Particulate Ceramics

7–477,395 (U.S. 5,039,312) Gas Separation With Rotating Plasma ARC Reactor

7–490,898 (U.S. 5,050,493) Bi-Directional Draining Pore Fluid Vessel

7–541,689 (U.S. 5,059,309) Ultrasonic Flotation System

7–582,690 (U.S. 5,060,751) Pneumatic Wall-Locking Geophone System
7–696,805 Method for Locating Metallic Nitrideww Inclusions in Metallic Alloy Ingots
7–734,002 Thrust Bolting; Roof Bolt Support Apparatus
7–736,344 Process for Forming A Hard Surface Coating
7–738,411 Chemical Process for the Catalytic Oxidation of Formaldehyde and Other Organic Compounds
7–750,685 Digital Roughness Gauge

Department of Agriculture

7–246,842 (U.S. 5,053,327) High Affinity Monoclonal Antibodies to Bowman-Birk Inhibitor and Immunoassay Methods
7–393,010 (U.S. 5,047,239) Biological Control of Fruit Rot
7–436,154 (U.S. 5,045,314) Control of Parasitic Nematode of Ova/Larvae with Bacillus Laterosporus
7–514,478 (U.S. 5,058,444) System for Analyzing Entrained Solids Such as Cotton or Seed
7–536,865 (U.S. 5,056,721) Method for Classifying Wheat Kernels as Hard or Soft
7–592,735 (U.S. 5,060,483) Twin Rinse Columns for Freeze Concentration of Rinsable Concentrates
7–598,256 Means and Method of Soil Water Desorption
7–675,979 Method and Apparatus for Forming Structural Components from Dry Wood Fiber Furnish
7–677,930 Power Density Measuring Apparatus and Method
7–691,873 Synthetic Bait for Delivery of Chemicals and Biologics
7–712,226 Greenhouse Illumination System
7–723,037 Attenuated Revertant Serotype 1 Marek's Disease Vaccine
7–725,320 Selection-Gene-Free Transgenic Plants
7–741,691 Non-Aflatoxigenic Aspergillus Parasiticus Species and Their Use in Controlling Aflatoxin Contamination
7–746,705 Bifunctional Protein from Carrots with Aspartokinase and Homoserine Dehydrogenase Activities
7–747,220 N-Acyl Loline Derivatives As Insecticides and Herbicides
7–749,347 Inhibition of Enzymatic Browning of Raw Fruit and/or Vegetable Juice
7–758,068 Uniform and Quantitative Evaluation of Aroma Emitting Substances
7–758,154 Lactose Hydrolysis by Mutant Streptococcus Thermophilus
7–764,732 System for Separating Particles in a Rotary Separator
7–764,738 Tensiometer Irrigation Valve
7–764,924 Constructed Wetlands to Control Nonpoint Source Pollution
7–765,732 PVC/Twine Dispenser for (+) – Disparlure
7–765,744 Measurement of Avian Embryo Movement in Intact Eggs
7–769,288 Use of Free Amines for Enhancement of Polycarboxylic Acid Based Cellulose Crosslinking Reactions
7–770,258 Adjustable Flume
7–770,806 Apparatus and Method for Applying Material to Agricultural Commodities

[FR Doc. 91–30099 Filed 12–16–91; 8:45 am]
BILLING CODE 3510–04–M

National Institute of Standards and Technology

Announcement of Meeting of National Conference on Weights and Measures

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Interim Meeting of the National Conference on Weights and Measures will be held January 12 through 17, 1992, at the Hyatt Regency Bethesda Hotel, Bethesda, MD. The meeting is open to the public.

The National Conference on Weights and Measures is an organization of weights and measures enforcement officials of the States, counties, and cities of the United States, and private sector representatives. The interim meeting of the conference, as well as the annual meeting to be held next July (a notice will be published in the **Federal Register** prior to such meeting), brings together enforcement officials, other government officials, and representatives of business, industry, trade associations, and consumer organizations to discuss subject that relate to the field of weights and measures technology and administration.

Pursuant to section 2(5) of its Organic Act (15 U.S.C. 272(5)), the National Institute of Standards and Technology acts as a sponsor of the National Conference on Weights and Measures in order to promote uniformity among the States in the complex of laws, regulations, methods, and testing equipment that comprises regulatory control by the States of commercial weighing and measuring.

DATES: The meeting will be held January 12–17, 1992.

LOCATION OF MEETING: Hyatt Regency Bethesda Hotel, Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: Dr. Carroll Brickenkamp, Executive Secretary, National Conference on Weights and Measures, P.O. Box 4025, Gaithersburg, Maryland 20885. Telephone: (301) 975–4005.

Dated: December 10, 1991.

John W. Lyons,

Director.

[FR Doc. 91–29994 Filed 12–16–91; 8:45 am]
BILLING CODE 3510–13–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of an Import Restraint Limit for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Nigeria

December 11, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit for the new agreement year.

EFFECTIVE DATE: January 1, 1992.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 566–5810. For information on embargoes and quota re-openings, call (202) 377–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

A Memorandum of Understanding (MOU) dated February 21, 1991 between the Governments of the United States and Nigeria establishes a limit for the period beginning on January 1, 1992 and extending through December 31, 1992.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the

implementation of certain of its provisions.

Philip J. Martello,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 11, 1991.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); pursuant to the Memorandum of Understanding dated February 21, 1991 between the Governments of the United States and Nigeria; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1992, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in the following categories, produced or manufactured in Nigeria and exported during the twelve-month period beginning on January 1, 1992 and extending through December 31, 1992, in excess of the following level of restraint:

Category	Twelve-month restraint limit
219, 220, 313, 314, 315, 317	28,090,000 square meters of which not more than 8,986,800 square meters shall be in Category 219, 8,986,800 square meters shall be in Category 220, 8,988,800 square meters shall be in Category 313, 8,988,800 square meters shall be in Category 314, 10,112,400 square meters shall be in Category 315 and 8,988,800 square meters shall be in Category 317

Imports charged to the category limit for the period January 1, 1991 through December 31, 1991 shall be charged against that level of restraint to the extent of any unfilled balance in the event the limit established for that period has been exhausted by previous entries, such goods shall be subject to the level set forth in this directive.

The limit set forth above is subject to adjustment in the future pursuant to the provisions of the current bilateral agreement between the Governments of the United States and Nigeria.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Philip J. Martello,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-30089 Filed 12-16-91; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF DEFENSE

Department of the Navy

CNO Executive Panel; Notice of Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app. 2), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel will meet January 15, 1992 from 9 a.m. to 5 p.m. at 4401 Ford Avenue, Alexandria, Virginia.

The purpose of this meeting is to review maritime envirionmental issues as they impact naval vessel construction and operation and shore establishment environmental protection. The agenda of the meeting will consist of discussions of key issues related to environmental cleanup and protection of naval facilities.

For further information concerning this meeting, contact: Judith A. Holden, Executive Secretary to the CNO Executive Panel, 4401 Ford Avenue, room 601, Alexandria, Virginia 22302-0268, Phone (703) 756-1205.

Dated: December 10, 1991.

Wayne T. Baucino

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-30028 Filed 12-16-91; 8:45 am]

BILLING CODE 3810-AE-F

DEPARTMENT OF ENERGY

[Docket No. PP-50-EA-H]

Waiver of Terms of Export Authorization

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of issuance of waiver of terms of export authorization.

SUMMARY: The DOE issued Central Power and Light Company a temporary order on December 10, authorizing a waiver of annual energy limits for the electricity export authorization contained in Docket No. PP-50-EA-H.

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202-586-9624 or Lise Howe (Program Attorney) 202-586-2900.

SUPPLEMENTARY INFORMATION: On November 26,1991, Central Power and Light Company (CPL) applied to the Department of Energy (DOE) for a waiver, on an interim basis, of certain terms of its existing electricity export authorization governing exports to Commission Federal de Electricidad (CFE), the Mexican national utility, over their 138-kilovolt (kV) Laredo to Nuevo Laredo Interconnection.

By order issued September 30, 1977, CPL and CFE were authorized to exchange electricity over three interconnections. The order was issued in accordance with a May 1, 1973, letter agreement between CPL and CFE that provided for exchanges of electricity in such a manner that the "exchange account" would have a zero balance at least once during the calendar year. CPL and CFE are not currently engaged in the type of energy exchanges contemplated by and provided for in the 1973 agreement. Furthermore, CFE has had to postpone several planned generating additions and has chosen to purchase capacity and energy from other utilities. As a result, CFE and CPL have entered into two additional power purchase agreements dated August 11, 1989, and April 30, 1991. The terms of these agreements make it impossible for CPL to comply with the zero balance requirements of the 1973 agreement, as reflected in the conditions of the 1977 export authorization.

Based on the above situation and CPL's assertion that it intends to make a filing, in the very near future, addressing all of its existing export authorizations governing CPL's points of interconnection with CFE, CPL requested a waiver of the terms of the 1977 export authorization. DOE has determined that issuance of such a temporary waiver is in the public interest, and issued such order on December 10, 1991. The order will remain in effect until December 31, 1992, or until such time as CPL receives from DOE a new export authorization, for which public participation has been sought.

Issued in Washington, DC on December 10, 1991.

Clifford P. Tomaszewski,

Acting Deputy Assistant Secretary for Fuels Programs, Fossil Energy.

[FR Doc. 91-30079 Filed 12-16-91; 8:45 am]

BILLING CODE 6450-01-M

Floodplain/Wetland Notice of Involvement for Two Proposed Process Water Outfalls to the Columbia River on the Hanford Site, Richland, Washington

AGENCY: Department of Energy.

ACTION: Notice of floodplain/wetlands involvement.

SUMMARY: The Department of Energy (DOE) proposes to construct two process water outfalls to the Columbia River in the 600 Area of the Hanford Site, Richland, Washington. Most activities related to the proposed projects would occur on the upland portion of the Hanford Site. Potential corridors of disturbance associated with pipelines on the designated wetlands or within the 100-year floodplain of the Columbia River would be kept as narrow as possible to reduce adverse impacts to these sensitive areas.

Pursuant to 10 Code of Federal Regulations part 1022 ("Compliance with Floodplain/Wetlands Environmental Review requirements"), DOE has determined that the construction of outfall piping systems would involve activities within a designated floodplain/wetland. In accordance with these regulations, DOE will prepare a floodplain/wetlands assessment for the proposed activities in conjunction with an environmental assessment. Maps and further information are available from DOE at the address shown below.

DATES: Comments are due on or before January 16, 1992.

ADDRESSES: Address comments to Mr. John P. Neath, P.O. Box 550, U.S. Department of Energy, Richland, Washington 99352.

FOR FURTHER INFORMATION CONTACT: Mr. Ken W. Bracken, Director, Waste Management Division, U.S. Department of Energy, P.O. Box 550, Richland, Washington 99352 (509) 376–1366. FAX: (509) 376–6540.

SUPPLEMENTARY INFORMATION: The Hanford Site, owned by the U.S. Government and managed by the DOE Richland, Field Office, occupies 560 square miles within the semiarid Pasco Basin of the Columbia Plateau in southeastern Washington. The entire Hanford Site is a controlled access area; 24-hour surveillance is maintained for the protection of the government property. Located north of the confluence of the Snake and Yakima Rivers with the Columbia River and north of the City of Richland, the Hanford Site is surrounded primarily by agricultural and range land. The cities of Richland, Kennewick, and Pasco, known as the Tri-Cities, constitute the nearest population center and are southeast of the Hanford Site. The Columbia River flows through the northern part of the Hanford Site, then turns to the south, forming the eastern boundary of the site. The Yakima River runs along a portion of the southern boundary of the site, and joins the Columbia River below the city of Richland.

Waste streams from the two proposed process water outfalls might either be released to the soil column on the upland portion of the Hanford Site or be discharged to the Columbia River. Discharge to the river might involve construction of the piping system within the 100-year floodplain of the Columbia River. The first waste stream would be composed of various separate effluent streams, all originating in the 200 Areas of the Hanford Site. After treatment, the effluent would meet all applicable release limits certified by the Washington State Department of Ecology and based on the National Pollutant Discharge Elimination System. The treated effluent streams might be discharged to the river at one of two possible locations: Effluent might be piped to an existing river outfall in the 100 N Area or to a new outfall to be located south of the 100 F Area on the Columbia River, approximately 20 miles upstream of the City of Richland. An environmental assessment would address relevant concerns associated with sitting a new outfall on the Columbia River.

The second waste stream consists of 300 Area process water effluent from various industrial facilities. If river discharge is determined to be the best alternative, effluent would be routed to the Columbia River directly north of the 300 Area. The effluent would meet applicable release limits certified by the Washington State Department of Ecology and based on the National Pollutant Discharge Elimination System.

If river discharge is selected, each outfall would consist of piping 8 to 21 inches in diameter buried to an average depth of five feet. Piping would lead to a diffuser (likely a multiport variable diameter horizontal reinforced concrete unit). The diffuser would be placed perpendicular to river flow and anchored to the river bottom using concrete weighted anchors. The proposed actions would be carried out by DOE, with appropriate permits from the U.S. Environmental Protection Agency, U.S. Army Corps of Engineers, State of Washington Departments of Ecology and Fisheries, and consultation with the National Park Service under Public Law 100–605, Hanford Reach Study Act. Maps and further information are available from DOE at the address shown above.

Paul D. Grimm,

Principal Deputy Assistant Secretary for Environmental Restoration and Waste Management.

[FR Doc. 91–30061 Filed 12–16–91; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. CP92–218–000, et al.]

Natural Gas Certificate Filings; Arkla Energy Resources, et al.

Take notice that the following filings have been made with the Commission:

1. Arkla Energy Resources, a division of Arkla, Inc.

[Docket No. CP92–218–000]

December 6, 1991.

Take notice that on December 3, 1991, Arkla Energy Resources, a division of Arkla, Inc. (AER), 525 Milam Street, Shreveport, Louisiana 71151, filed in Docket No. CP92–218–000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205), for authorization to operate certain existing delivery facilities located in Arkansas, Oklahoma, Louisiana, Kansas and Texas as jurisdictional facilities to provide jurisdictional services, including transportation services under subpart G of part 284 of the Commission's Regulations, under its blanket certificate issued in Docket No. CP82–384–000, *et al.*, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that the delivery facilities consist of ten 2-inch, 4-inch, 6-inch and 8-inch taps, meters and appurtenant facilities located in White, Independence, Hot Springs, and Mississippi Counties, Arkansas; Grant and Caddo Counties, Oklahoma; Bossier Parish, Louisiana; Sedgewick and Sumner Counties, Kansas; and Cass County, Texas. It is further stated that AER completed construction of the facilities in 1987 and 1988 at a total cost of $1,278,572.

AER states that the delivery facilities were originally constructed solely to provide services authorized under section 311 of the Natural Gas Policy Act and subpart B of the Commission's Regulations. AER further states that information applicable to each facility including the location, completion date, volumes and amount of cost to construct

has been provided by AER in appendix A to the filing.

Comment date: January 21, 1992, in accordance with Standard Paragraph G at the end of this notice.

2. Inland Oil & Gas Corp.

[Docket No. CI92-13-000]

December 9, 1991.

Take notice that on December 2, 1991, Inland Oil & Gas Corp. (Inland) of 2300-1066 West Hastings Street, Vancouver, British Columbia V6E 3G3 filed an application pursuant to sections 4 and 7 of the Natural Gas Act and the Federal Energy Regulatory Commission's (Commission) regulations thereunder for an unlimited-term blanket certificate with pregranted abandonment authorizing sales for resale in interstate commerce of natural gas subject to the Commission's NGA jurisdiction, including imported natural gas, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Comment date: December 26, 1991, in accordance with Standard Paragraph J at the end of this notice.

3. O & R Energy, Inc.

[Docket No. CI88-496-001]

December 9, 1991.

Take notice that on November 27, 1991, O & R Energy, Inc. (O & R), filed an application pursuant to sections 4 and 7 of the Natural Gas Act and the Federal Energy Regulatory Commission's (Commission) regulations thereunder to amend its unlimited-term blanket certificate with pregranted abandonment previously issued by the Commission in Docket No. CI88-496-000 to (1) effect a change of name from O & R Energy Development, Inc. and (2) to include authorization for the sale for resale in interstate commerce of imported gas, gas purchased under any existing or subsequently approved pipeline blanket certificate authorizing interruptible sales for resale of surplus system supply (ISS gas), and gas purchased from non-first sellers including intrastate pipelines and local distribution companies, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Comment date: December 26, 1991, in accordance with Standard Paragraph J at the end of the notice.

4. Marathon Oil Company

[Docket No. CI63-271-001]

December 9, 1991.

Take notice that on February 27, 1990, Marathon Oil Company, (Marathon) of P.O. Box 3128, Houston, Texas 77252, filed an application pursuant to sections 7(b) and 16 of the Natural Gas Act and the Federal Energy Regulatory Commission's (Commission) regulations thereunder requesting that the Commission clarify that, because its sale of gas to Northern Natural Gas Company (Northern) is deregulated under the Natural Gas Wellhead Decontrol Act of 1989 (Decontrol Act), no abandonment authorization is required to terminate the sale. Alternatively, Marathon requests that the Commission authorize abandonment of the sale to Northern, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Marathon was authorized in Docket No. CI63-271 to make a sale to Northern from the Yates Casinghead Gas Plant in Pecos County, Texas, under a gas purchase contract dated October 10, 1961. The contract provides for a term ending June 30, 1981. According to Marathon, since July 1, 1976, all gas subject to that contract has been used as fuel gas or injection gas for pressure maintenance purposes and there have been no sales to Northern since that date.

Marathon argues that, since the contract expired in 1981, the gas from the Yates Plant was not subject to a contract on the date of enactment of the Decontrol Act, and is no longer subject to the Commission's Natural Gas Act jurisdiction. Therefore, Marathon requests that the Commission clarify that Marathon does not need authorization to terminate its sale to Northern.

Comment date: December 26, 1991, in accordance with Standard Paragraph J at the end of this notice.

5. Questar Pipeline Company

[Docket No. CP92-214-000]

December 10, 1991.

Take notice that on November 27, 1991, Questar Pipeline Company (Questar), 79 South State Street, Salt Lake City, Utah 84111, filed in Docket No. CP92-214-000, a request pursuant to §§ 157.205 and 157.212 of the Commission's Regulations and Questar's blanket certificate issued in Docket No. CP82-491-000 pursuant to section 7 of the Natural Gas Act for authorization to convert the jurisdictional status of its existing Amoco Production Company (Amoco) Ryckman Creek delivery point, located in Uinta County, Wyoming from that of a NGPA § 311 facility to a NGA § 7(c) facility consistent with the Commission's Order No. 537 issued September 20, 1991, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Questar states that the Ryckman Creek delivery point facility consists of one 2-inch meter run and minor appurtenant facilities. The Ryckman Creek delivery point was placed in service on October 10, 1988, and the transportation of Volumes commenced on October 15, 1988. Questar states that converting the jurisdictional status of the Ryckman Creek delivery point facility will allow it to permanently provide the complete array of open-access transportation services for Amoco and allow Amoco to use a variety of additional natural-gas suppliers to meet its Ryckman Creek processing plant fuel gas and heating requirements. It is stated that Amoco expects future peak-day and annual requirements at the delivery point to approximate 1,000 Mcf per day and 150,000 Mcf per year, respectively. No change in the level of the delivery of transportation volumes is proposed. Questar states that it has sufficient pipeline capacity to deliver the specified volumes to Amoco without detriment or disadvantage to its other customers. Questar's FERC Gas Tariff does not prohibit the addition of new delivery points.

Comment date: January 24, 1992, in accordance with Standard Paragraph G at the end of this notice.

7. National Fuel Gas Supply Corporation

[Docket No. CP92-222-000]

December 10, 1991.

Take notice that on December 6, 1991, National Fuel Gas Supply Corporation (National), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP92-222-000 a request pursuant to §§ 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (19 CFR 157.205, 157.211) for authorization to construct and operate sales tap facilities for the delivery of gas for the account of Clarion River Gas (CRG) under National's blanket certificate issued in Docket No. CP83-4-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

National proposes to construct and operate two sales tap facilities in Barnett Township, Forest County, Pennsylvania, for the account of an existing wholesale customer, CRG. National states that the first sales tap

would be a temporary facility located on National's Line K–104 with proposed deliveries which are estimated to be 1,332 Mcf annually. National further states that the second facility would be a permanent tap which would be located on National's Line QM 95 with proposed deliveries which are estimated to be 2,644 Mcf annually. National advises that the gas would be sold pursuant to the terms of its FERC Rate Schedule RQ.

Comment date: January 24, 1992, in accordance with Standard Paragraph G at the end of this notice.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Standard Paragraph

J. Any person desiring to be heard or make any protest with reference to said filings should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, .214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30005 Filed 12–16–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91–161–004]

Columbia Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff

December 10, 1991.

Take notice that on November 27, 1991, Columbia Gas Transmission Corporation (Columbia) filed a motion to place its suspended rates in this proceeding into effect on December 1, 1991, and tendered for filing the revised tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1 and Original Volume No. 2. The revised tariff sheets bear an issue date of November 27, 1991, and a proposed effective date of December 1, 1991.

The revised filing is being made in accordance with the Commission's order issued June 28, 1991, in these proceedings and § 154.67(a) of the Commission's Regulations.

Columbia requests a 30-day waiver of § 154.63(a)(2) of the Commission's Regulations in order to include costs associated with certain "Global Settlement" and other facilities that will not be in service on November 30, 1991.

Copies of the filing were served by the company upon each of its wholesale customers, interested state commissions and each of the parties set forth on the Official Service List in the consolidated proceedings.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Union Center Plaza Building, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before December 17, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of Columbia's filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30006 Filed 12–16–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91–164–002]

Granite State Gas Transmission, Inc.; Proposed Changes in Rates

December 11, 1991.

Take notice that on November 29, 1991, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581, tendered for filing the following revised tariff sheet in its FERC Gas Tariff, Second Revised volume No. 1 and First Revised Volume No. 2, containing changes in rates and other tariff provisions for effectiveness on December 1, 1991:

Second Revised Volume No. 1

Second Substitute Seventh Revised Sheet No. 21
Substitute Second Revised Sheet No. 36
Second Revised Sheet No. 123
Substitute First Revised Sheet No. 222

First Revised Volume No 2

Substitute Second Revised Sheet No. 28

According to Granite State, the above identified revised tariff sheets comprise its motion rates in this proceeding. Granite State states that it filed revised rates on May 31, 1991, with further revisions on June 17, 1991, for effective on July 1, 1991. It is stated that the Commission accepted the filing in an order issued June 28, 1991, subject to refund and suspended it until December 1, 1991. The order also initiated a hearing with respect to the filing. According to Granite State, since the proceeding initiated by the Commission's order of June 28, 1991 has not been concluded at the end of the suspension period, it is authorized pursuant to section 4(e) of the Natural Gas Act to move its suspended rates into effect.

Granite State further states that the motion rates reflect a voluntary reduction in the suspended rates. It is further stated that the initial rates filed in this proceeding and suspended by the Commission's order proposed an annual increase in the non-gas components of Granite State's jurisdictional rates of approximately $880,000 and that the motion rates reflect an annual revenue increase of approximately $424,000 in the non-gas rate components. It is also stated that the motion rates reflect an increase in billing determinants and annual throughout because of increased jurisdictional sales authorized, effective November 1, 1991, in Docket No. CP91–2373.

It is stated that the proposed rate changes are applicable to Granite State's jurisdictional services rendered to Bay State Gas Company and Northern Utilities, Inc. Granite State further states that copies of its filings were served upon its customers, the regulatory commissions of the States of Maine, Massachusetts and New Hampshire and the intervenors in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission,

825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30010 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TQ92-2-16-000, TA92-1-16-001]

National Fuel Gas Supply Corp.; Proposed Changes in FERC Gas Tariff

December 11, 1991

Take notice that on December 2, 1991, National Fuel Gas Supply Corporation ("National") submits for filing Substitute Seventeenth Revised Sheet No. 5, as part of its FERC Gas Tariff, Second Revised Volume No. 1, to become effective on January 1, 1992.

National states that the purpose of this filing is to reflect a revision to the current adjustment shown in National's Annual Purchased Gas Cost Adjustment ("PGA") filed on October 31, 1991, in Docket No. TA92-1-16-000. The tariff sheet reflects a commodity current adjustment of 32.96 cents per dekatherm ("Dt"), from National's October quarterly PGA filed on August 30, 1991 in Docket Nos. TQ92-1-16-000 and TM92-1-16-000. The revised RQ and CD sales commodity rate of 300.83 cents per Dt is based upon a current average cost of purchased gas of 285.29 cents per Dt (in unit of purchases), or 291.28 cents per Dt (in unit of sales).

National further states that copies of this filing were served on National's jurisdictional customers and on the Regulatory Commissions of the States of New York, Ohio, Pennsylvania, Delaware, Massachusetts and New Jersey.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 214 or 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All such motions to intervene or protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30007 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM-92-2-37-003]

Northwest Pipeline Corporation; Proposed Change in FERC Gas Tariff

December 11, 1991.

Take notice that on November 27, 1991, Northwest Pipeline Corporation ("Northwest") tendered for filing and acceptance the following tariff sheets:

Second Revised Volume No. 1

1st Rev Tenth Revised Sheet No. 10
1st Rev Eleventh Revised Sheet No. 10
Substitute Twelfth Revised Sheet No. 10
2nd Rev Twelfth Revised Sheet No. 10
2nd Sub Thirteenth Revised Sheet No. 10
1st Rev Fourteenth Revised Sheet No. 10
1st Rev Tenth Revised Sheet No. 11
1st Rev Eleventh Revised Sheet No. 11
Substitute Twelfth Revised Sheet No. 11
2nd Rev Twelfth Revised Sheet No. 11
2nd Sub Thirteenth Revised Sheet No. 11
1st Rev Sixth Revised Sheet No. 13
Substitute Seventh Revised Sheet No. 13
2nd Rev Seventh Revised Sheet No. 13
2nd Sub Eighth Revised Sheet No. 13

First Revised Volume No. 1-A

1st Rev Sixth Revised Sheet No. 201
Sub Seventh Revised Sheet No. 201
2nd Rev Seventh Revised Sheet No. 201
2nd Sub Eighth Revised Sheet No. 201

Original Volume No. 2

1st Rev Twenty-Third Rev Sheet No. 2.3
1st Rev Twenty-Fourth Rev Sheet No. 2.3
Sub Twenty-Fifth Rev Sheet No. 2.3

Northwest states that the purpose of this filing is to recalculate and restate the Commodity SSP Surcharge on all previously Commission approved tariff sheets, which have a July 1, 1991 or October 1, 1991 effective date, to comply with the Commission's letter order and Order Denying Rehearing, issued by the Commission on September 30, 1991 and November 14, 1991, respectively, in the above docket. Northwest has restated the Commodity SSP Surcharges contained in the above sheets using annual billing determinants of 568.6 TBtu rather than 450 TBtu, as previously filed.

Northwest has challenged the Commission's orders requiring it to calculate its Commodity SSP Surcharge based upon billing determinants other than those approved in the settlement of Phase I of Docket No. RP88-47. Northwest reserves the right and gives notice that it will refile its Commodity SSP Surcharge rates for any affected periods beginning July 1, 1991, should Northwest ultimately be successful in its court appeals.

Northwest states that a copy of this filing has been served upon all parties of record in Docket No. RP89-137 and upon Northwest's jurisdictional customer list and affected state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30011 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TQ92-1-55-001 and TM92-2-55-000]

Questar Pipeline Co.; Tariff Filing

December 11, 1991.

Take notice that Questar Pipeline Company, on November 27, 1991 tendered for filing and acceptance the following tariff sheets to its FERC Gas Tariff:

Substitute Fifteenth Revised Sheet No. 12 to Original Volume No. 1 to be effective December 1, 1991.
Sixteenth Revised Sheet No. 12 to Original Volume No. 1,
Seventeenth Revised Sheet No. 5 to Original Volume No. 1-A and
Eighth Revised Sheet No. 8 to Original Volume No. 3 to be effective January 1, 1992.

Questar states that this filing (1) revises the Statement of Rates filed in its November 6, 1991, purchase gas cost adjustment filing by reflecting new base rates as filed in Questar's November 15, 1991, compliance filing in Docket No. RP91-140-008 and (2) implements the 1992 Gas Research Institute charge authorized by the Commission on October 1, 1991.

Questar requests an effective date of December 1, 1991, for Substitute

Fifteenth Revised Sheet No. 12 and January 1, 1992, for the tariff sheets submitted to implement the GRI charge.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 385.211 and 385.214 of the Commission's Rules of Practice and Procedure 18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30009 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-42-000]

Ringwood Gathering Co.; Petition for Waiver

December 11, 1991.

Take notice that on December 4, 1991, Ringwood Gathering Company (Ringwood) filed with the Federal Energy Regulatory Commission a request for a continued waiver of the PGA regulations in 18 CFR 154.301 through 154.310 for its currently scheduled PGA Docket No. TQ92-1-38-000. Ringwood also requests a continued waiver to maintain the existing quarterly PGA rates in Ringwoods' last quarterly filing (TQ91-3-38-000) excluding the surcharge adjustment which was effective through September 30, 1991. Ringwood states that it anticipates no sales will be made under the PGA mechanism.

Ringwood submitted Eighth Revised Sheet No. 4C Superceding Seventh Revised Sheet No. 4C to maintain its prior rates excluding the surcharge rates. The tariff sheet has a proposed effective date of January 1, 1992.

Ringwood states that copies of the filing have been mailed to Williams Natural Gas Company, Oklahoma Natural Gas Company, and interested State regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before December 17, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30013 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-4-8-000]

South Georgia Natural Gas Company; Proposed Changes to FERC Gas Tariff

December 11, 1991.

Take notice that on December 4, 1991, South Georgia Natural Gas Company (South Georgia) tendered for filing Eighty-First Revised Sheet No. 4 and Eleventh Revised Sheet No. 43 to its FERC Gas Tariff, First Revised Volume No. 1. Eighty-First Revised Sheet No. 4 is being filed pursuant to the Purchased Gas Cost Adjustment (PGA) provision set out in Section 14 of South Georgia's FERC Gas Tariff with a proposed effective date of January 1, 1992. Eleventh Revised Sheet No. 43, Index of Purchasers, reflects the conversion by certain of South Georgia's customers from firm sales service to firm transportation service. The proposed effective date for Eleventh Revised Sheet No. 43 is also January 1, 1992.

South Georgia states that Eighty-First Revised Sheet No. 4 reflects a revised Current Adjustment computed in accordance with § 154.305(c) of the Federal Energy Regulatory Commission's (Commission) Regulations. The Current Adjustment, which is proposed to be in effect from January 1, 1992, through March 31, 1992, reflects an increase in jurisdictional revenues of approximately $1.4 million which is attributable to an increase in the demand component of $9.85 per Mcf and an increase in the commodity component of $.39 per MMBtu from South Georgia's out-of-cycle PGA filing in Docket No. TQ92-3-8-000.

South Georgia states that copies of the filing will be served upon all of South Georgia's jurisdictional purchasers, interested state commissions and interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure 18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30012 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-32-000]

Southern Natural Gas Co. and South Georgia Natural Gas Co.; Petition for Limited Waiver

December 11, 1991.

Take notice that on November 22, 1991, Southern Natural Gas Company (Southern) and South Georgia Natural Gas Company (South Georgia) petition the Commission for a limited waiver of certain storage tariff provisions which limit the availability of the storage service to gas purchased from Southern and South Georgia.

Southern requests a limited waiver of the requirement contained in section 2.1 of Exhibit B of Rate Schedules STS-1 that a customer make volumes available for delivery to storage under Rate Schedules CSS-1 and CSS-2 by purchasing such volumes from Southern and of the requirement contained in section 3.1 of Exhibit B of Rate Schedules CSS-1 and CSS-2 that storage gas shall be provided pursuant to Rate Schedule STS-1. South Georgia requests a limited waiver of the same provisions set out in section 2.1 of Exhibit B of its ST-1 and ST-2 Rate Schedules and in section 3.1 of Exhibit B to its SS-1 and SS-2 Rate Schedules.

Southern and South Georgia request that the waivers be granted for a period ending on the earlier of October 31, 1992, or the date the Commission approves, on a basis acceptable to all parties, the Stipulation and Agreement dated July 30, 1991, in Docket No. CP89-1721.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR

385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before December 17, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30014 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP89-629-009 and CP90-639-005]

Tennessee Gas Pipeline Co.; Compliance Filing

December 11, 1991.

Take notice that on November 8, 1991, Tennessee Gas Pipeline Company (Tennessee), in compliance with the Federal Energy Regulatory Commission's (Commission) October 9, 1991 order in the above-referenced dockets tendered for filing revised Incremental Pressure Charge (IPC) for Orchard Gas Corporation (Orchard Gas) on behalf of MASSPOWER.

Tennessee states that the revised filing is consistent with the Commission's concerns discussed in the October 9 order with one exception. Tennessee states that with regard to the inclusion of certain fixed costs, notably depreciation expense, return, and taxes, Tennessee submits that the fixed costs are already included in the NET-EU tariff rate approved by the Commission.

Tennessee states that it has served a copy of the filing on each person designated on the official service list compiled by the Company in the above-referenced dockets.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30018 Filed 12-16-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-35-000]

West Texas Gas, Inc.; Filing

December 11, 1991.

Take notice that on December 3, 1991, West Texas Gas, Inc. ("WTG") filed Twenty-Sixth Revised Sheet No. 3a to its FERC Gas Tariff, Original Volume No. 1, proposed to be effective January 1, 1991. Twenty-Sixth Revised Sheet No. 3a and the accompanying explanatory schedules constitute WTG's quarterly PGA filing submitted in accordance with the Commission's purchased gas adjustments regulations.

WTG states that copies of the filing were served upon WTG's customers and interested state commissions.

Any persons desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before December 18, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30008 Filed 12-16-91; 8:45 am]

BILLING CODE 6710-01-M

Office of Fossil Energy

[Docket No. PP-93]

Application for a Presidential Permit; Southwestern Public Service Company

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of Receipt of Application for a Presidential Permit in Docket No. PP-93; Southwestern Public Service Company.

SUMMARY: Southwestern Public Service Company has applied for a Presidential permit to construct a new electric transmission line at the U.S./Mexican border.

DATES: Comments, protests or requests to intervene must be submitted on or before January 16, 1992.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Electricity (FE-52), Office of Fuels Programs, Office of Fossil Energy, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

Docket Number PP-93 should appear clearly on the enevelope and the document contained therein.

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202-586-9624 or Lise Howe (Program Attorney) 202-586-2900.

SUPPLEMENTARY INFORMATION: The construction, connection, operation, and maintenance of facilities at the international border of the United States for the transmission of electrical energy is prohibited in the absence of a Presidential permit pursuant to Executive Order No. 12038. Exports of electricity from the United States to a foreign country also are regulated and require authorization under section 202(e) of the Federal Power Act.

On November 22, 1991, Southwestern Public Service Company (SPS) applied to the Department of Energy (DOE) for a Presidential permit to construct, connect, operate, and maintain two, 345-kilovolt (kV) transmission lines which would extend approximately 208.5 miles from the site of the Eddy County Interchange west, southwest, to a proposed crossing of the international boundary at a point in New Mexico situated west of El Paso, Texas. The proposed line would interconnect at the international boundary with a proposed 345-kV transmission line owned and operated by the Comision Federal de Electricidad (CFE), the Mexican national utility. SPS also proposes to construct a new substation facility near the site of an existing interchange operated by SPS in Eddy County, New Mexico.

In its application for a Presidential permit, SPS stated that the proposed interconnection would facilitate sales of electricity from SPS to the Quixx Corporation, an operating subsidiary of SPS, and Pecten Coal International, Inc., which propose to market electricity to CFE as a joint venture. The granting of a Presidential permit does not automatically render approval for the exporting of electricity; a separate export authorization must be obtained by the exporting company.

Procedural Matters

Any person desiring to be heard or to protest this application should file a petition to intervene or protest at the address provided above in accordance with § § 385.211 or 385.214 of the Rules of Practice and Procedures (18 CFR 385.211, 385.214).

Any such petitions and protests should be filed with the DOE on or before the date listed above. Additional copies of such petitions to intervene or protests also should be filed directly with: Mr. Olon Plunk, Manager, Environmental Affairs, Southwestern Public Service Company, P.O. Box 1261, Amarillo, Texas 79170.

Pursuant to 18 CFR 385.211, protests and comments will be considered by the DOE in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene under 18 CFR 385.214. Section 385.214 requires that a petition to intervene must state, to the extent known, the position taken by the petitioner and the petitioner's interest in sufficient factual detail to demonstrate either that the petitioner has a right to participate because it is a State Commission; that is has or represents an interest which may be directly affected by the outcome of the proceeding, including any interest as a consumer, customer, competitor, or security holder of a party to the proceeding; or that the petitioner's participation is in the public interest.

A final decision will be made on this application after a determination is made by the DOE that the proposed action will not impair the reliability of the U.S. electric power supply system.

Before a Presidential permit may be issued, the environmental impacts of the proposed DOE action (i.e., granting the Presidential permit, with any conditions and limitations, or denying it) must be evaluated pursuant to the National Environmental Policy Act of 1969 (NEPA). The NEPA compliance process is a cooperative, non-adversarial process involving members of the public, state governments and the Federal government. The process affords all persons interested in or potentially affected by the environmental consequences of a proposed action an opportunity to present their views, which will be considered in the preparation of the environmental documentation for the proposed action. Intervening and becoming a party to this proceeding will not create any special status for the petitioner with regard to the NEPA process. Should a public proceeding be necessary in order to comply with NEPA, notice of such activities and information on how the public can participate in those activities will be published in the **Federal Register**, local newspapers and public libraries and/or reading rooms in the vicinity of the electric transmission facilities.

Copies of this application will be made available, upon request, for public inspection and copying at the Department of Energy, room 3F-070, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, from 9 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on December 10, 1991.

Anthony J. Como,

Director, Office of Coal & Electricity, Office of Fuels Programs.

[FR Doc. 91-30080 Filed 12-16-91; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-44578; FRL-4006-3]

TSCA Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the receipt of test data on tributyl phosphate (TBP) (CAS No. 126-73-8), submitted pursuant to a final test rule. Test data were also received on C.I. disperse blue 79:1 (CAS No. 3618-72-2), and the following phthalate esters: di(heptyl, nonyl, undecyl) (D711P) (CAS No. 68515-42-4), diundecyl (DUP) (CAS No. 3648-20-2), dihexyl (DHP) (CAS No. 68515-50-4 and 84-75-3), di-n-butyl (BnBP) (CAS No. 84-74-2) and dimethyl (DMP) (CAS No. 131-11-3) submitted pursuant to a testing consent order. All data were submitted under the Toxic Substances Control Act (TSCA). Publication of this notice is in compliance with section 4(d) of TSCA.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Section 4(d) of TSCA requires EPA to publish a notice in the **Federal Register** reporting the receipt of test data submitted pursuant to test rules promulgated under section 4(a) within 15 days after it is received. Under 40 CFR 790.60, all TSCA section 4 consent orders must contain a statement that results of testing conducted pursuant to these consent orders will be announced to the public in accordance with section 4(d).

I. Test Data Submissions

Test data for TBP were submitted by the Tributyl Phosphate Task Force, affiliated with the Synthetic Organic Chemical Manufacturers Association Inc., on behalf of the test sponsors and pursuant to a test rule at 40 CFR 799.4360. They were received by EPA on September 5 and 27, and November 18, 1991. The September 5th submission describes an acute *in-vivo* cytogenetics assay in rats. The September 27th submission describes the chronic toxicity of TBP to *daphnia magna* under flow-through test conditions. The November 18th submission describes the acute flow-through toxicity exposure of TBP to *Gammarus pseudolimnaeus*. Health effects and environmental effects testing is required by this test rule. This chemical is used in aircraft hydraulic fluids; for extraction and separation processes in the plutonium uranium reduction extraction process; as a deformer in the paper industry; in textile sizers, inks, and lacquers; and as a plasticizer.

Test data for C.I. disperse blue were submitted by the U. S. Operating Committee of the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry on behalf of the participating companies of record, and pursuant to a consent order at 40 CFR 799.5000. They were received by EPA on October 11, 1991. The submission describes the disposition and metabolite characterization following peroral dose administration to male and female sprague-dawley rats. Health effects testing is required by this consent order. This chemical is used for dyeing or printing polyester fibers.

Test data for the phthalates esters (D711P), (DUP), (DHP), (DnBP) and (DMP) were submitted by the Chemical Manufacturers Association on behalf of the test sponsors and pursuant to a testing consent order at 40 CFR 799.5000. They were received by EPA on October 28, November 4, and 7, 1991. The submissions describe the early life-stage toxicity of (D711P), (DUP), (DHP), (DnBP) and (DMP) to the rainbow trout *Oncorhynchus mykiss* under flow-through conditions. Environmental effects testing is required by this consent order. These chemicals are used

primarily as plasticizers in a wide variety of plastic products.

EPA has initiated its review and evaluation process for these data submissions. At this time, the Agency is unable to provide any determination as to the completeness of the submissions.

II. Public Record

EPA has established a public record for this TSCA section 4(d) receipt of data notice (docket number OPTS-44578). This record includes copies of all studies reported in this notice. The record is available for inspection from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, rm. NE-G004, 401 M St., SW., Washington, DC 20460.

Authority: 15 U.S.C. 2603.

Dated: December 9, 1991.

Charles M. Auer,

Director, Existing Chemical Assessment Division, Office of Toxic Substances.

[FR Doc. 91-30088 Filed 12-16-91; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

December 4, 1991.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, Downtown Copy Center, 1114 21st Street NW., Washington, DC 20036, (202) 452-1422. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0206.

Title: Part 21—Domestic Public Fixed Radio Services (§§ 21.201, 21.307, 21.406, 21.708, 21.808).

Action: Extension.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of Response: Recordkeeping requirement and on occasion reporting.

Estimated Annual Burden: 2,272 responses, .44 hours average burden per response, 1,000 hours total annual burden; 100 recordkeepers, 2 hours average burden per recordkeeper, 200 hours total annual burden.

Needs and Uses: The Communications Act of 1934, as amended, requires the FCC to license all common carrier microwave stations and to establish pertinent rules to assure proper operation. Section 21.201 requires the posting of station authorizations to demonstrate to the public, station owners and FCC field inspectors that the station is properly licensed. Section 21.307, equal employment opportunities, is required to assure nondiscrimination in recruiting, selection and hiring, promoting and other areas of employment practices. Such recordkeeping facilitates the timely filing by the licensee or permittee of the equal employment annual report (FCC Form 395). Section 21.406 requires the submission of developmental reports upon completion of projects authorized for developmental purposes to assure the compliance with the developmental authorization and for determination of the feasibility of such proposal for rendering telecommunication services. Sections 21.708 and 21.808 require notification to the FCC and its field offices of impending operation of microwave stations at temporary locations for periods less than 6 months. Notification is necessary to assure technical and legal compliance with part 21 since specific frequencies are not assigned to licensees.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91-30050 Filed 12-16-91; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

December 6, 1991.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, Downtown Copy Center, 1114 21st Street, NW., Washington, DC 20036, (202) 452-1422. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

Note: The Commission had requested emergency OMB review and approval by November 27, 1991.

OMB Number: None.

Title: Time Brokerage Agreement Survey.

Action: New collection.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of Response: Other: One-time survey.

Estimated Annual Burden: 300 responses; 1 hour average burden per response; 300 hours total annual burden.

Needs and Uses: This collection of information is needed for the Commission to assess the nature and extent of time brokerage agreements, which are reported to be a growing phenomenon in the commercial broadcast industry, and the degree to which they comply with the Commission rules and policies. The information will be used by the FCC in gauging compliance with its time brokerage rules and policies and deciding what rules may be needed to control the spread of time brokerage agreements if the survey shows that there is a growing number of time brokerage stations and that problems of loss of licensee control or disregard for localism and diversity are resulting. At this point, the FCC does not know whether there is significant amount of time brokerage to be a problem.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Attachment—Data Gathering Methodology

FCC will gather information regarding commercial broadcast stations' time brokerage activities three ways: By reviewing broadcast licensees' records (required by OMB approved rules); by observing the stations' operations; and interviews. FCC already has the authority to review station records and to inspect stations. However, it wants OMB approval for the interviews. Listed below are the three ways we will gather data. We request OMB approval for the interview questions, Part III (and, to the extent necessary, for Parts I and III as well).

**Part I—Review of Licensee's Records*

Was the complete public inspection file at the studio?

Is the issue/program list complete and available?

Does the licensee have a written brokerage agreement? With whom?

** Part II—Observations of FCC Inspector*

Is there more than one person employed at the station during business hours?
Is station management available within an hour?
Is there a transmitter operator on duty?
Is the main studio closed during business hours?
Does the station have the facilities to originate programming?
Are any other indications of loss of control by the licensee apparent?

Part III—Station Management Interview Survey Questions

Is a third party paying employees salaries?
Is the station simulcasting in the same market more than 25% of the time? (How many hours per day are simulcast?)
Is the station simulcasting in an adjacent market?
Does this station provide or receive time brokerage programming?
How many hours per week does the station operate?
How many hours per week is operation brokered?
What is the average percentage of time brokered for the past year?

Note: the information may be collected by telephone rather than at the stations. If this occurs, only Part III information will be collected.

[FR Doc. 91-30051 Filed 12-16-91; 8:45 am]
BILLING CODE 6712-01-M

[Report No. 1868]

Petitions for Reconsideration and Clarification and Application for Review of Actions in Rulemaking Proceedings

December 11, 1991.

Petitions for reconsideration have been filed in the Commission rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of these documents are available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC, or may be purchased from the Commission's copy contractor Downtown Copy Center (202) 452-1422. Oppositions to these petitions must be filed January 3, 1992. See 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of § 73.202(b) Table of Allotments, FM Broadcast Stations. (Jackson, Alabama) (RM-7489).

Number of Petitions Received: 6.

Subject: Provision of Access for 800 Services. (CC Docket No. 86-10).

Number of Petitions Received: 6

Subject: Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations (Sonora, California) (MM Docket No. 89-108; RM No. 6606).

Number of Petitions Received: 1.

Subject: Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations. (Elkins, West Virginia, Mountain Lake Park, and Westernport, Maryland) (MM Docket No. 89-580, RM Nos. 6977, 7177 and 7446).

Number of Petitions Received: 1.

Subject: Amendment of parts 21, 43, 74, 78 and 94 of the Commission's Rules Governing Use of the Frequencies in the 2.1 and 2.5 GHz Bands Affecting: Private Operational-Fixed Microwave Service, Multipoint Distribution Service, Multichannel Multipoint Distribution Service, Instructional Television Fixed Service, and Cable Television Relay Service. (GEN. Docket No. 90-54).

Number of Petitions Received: 1.

Subject: Competition in the Interstate Interexchange Marketplace. (CC Docket No. 90-132).

Number of Petitions Received: 13.

Subject: Amendment of § 73.202(b) Table of Allotments, FM Broadcast Stations. (Homerville, Lakeland and Statenville, Georgia) (MM Docket No. 90-214; RM No. 7101 and 7226).

Number of Petitions Received: 1.

Subject: Policies and Rules Concerning Interstate 900 Telecommunications services. (CC Docket No. 91-65).

Number of Petitions Received: 11.

Application for Review

Subject: Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations. (Eatonton and Sandy Springs, Georgia; Anniston and Lineville, Alabama) (MM Docket Nos. 89-585, 7035 and 7320).

Number of Applications Received: 1.

Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 91-30049 Filed 12-16-91; 8:45 am]
BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Agency Information Collection Submitted to the Office of Management and Budget for Clearance

The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following information collection package for clearance in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35).

Type: Extension of 3067-0147.

Title: Report to Submit Technical or Scientific Data to Correct Mapping Deficiencies unrelated to Community-wide Elevation Determinations.

Abstract: Any owner or lessee of property in communities with mapped Special Flood Hazard Areas who believes their property should not be shown within a SFHA on the National Flood Insurance Program Flood Hazard Boundary Maps or Flood Insurance Rate Maps has the right to submit the technical or scientific data which shows the map to be incorrect. FEMA's Federal Insurance Administration reviews the information and issues a letter of map correction, if warranted.

Type of Respondents: Individuals and households.

Estimate of Total Annual Reporting and Recordkeeping Burden: 81,504 Hours.

Number of Respondents: 3,396.

Estimated Average Burden Hours Per Response: 24 Hours.

Frequency of Response: On occasion.

Copies of the above information collection request and supporting documentation can be obtained by calling or writing the FEMA Clearance Officer, Linda Borror, (202) 646-2624, 500 C Street, SW., Washington, DC 20472.

Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: The FEMA Clearance Officer at the above address; and to Gary Waxman, (202) 395-7340, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503 within four weeks of this notice.

Dated: December 5, 1991.
Wesley C. Moore,
Director, Office of Administrative Support.
[FR Doc. 91-30068 Filed 12-16-91; 8:45 am]
BILLING CODE 6718-01-M

[FEMA-925-DR]

Republic of the Marshall Islands; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency.
ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Republic of the Marshall Islands (FEMA-925-DR), dated

* FCC currently has authority for these areas of review

December 6, 1991, and related determinations.

DATES: December 6, 1991.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646–3614.

NOTICE: Notice is hereby given that, in a letter dated December 6, 1991, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Public Law 93–288, as amended by Public Law 100–707), as follows:

I have determined that the damage in certain areas of the Republic of the Marshall Islands, resulting from Typhoon Zelda on November 28–29, 1991, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the Republic of the Marshall Islands.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Major P. May of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Republic of the Marshall Islands to have been affected adversely by this declared major disaster:

The islands of Ebeye Island, Kwajalein Atoll, Lae Atoll, and Ujae Atoll for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 91–30066 Filed 12–16–91; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–926–DR]

Federated States of Micronesia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Federated States of Micronesia (FEMA–926–DR), dated December 10, 1991, and related determinations.

DATES: December 10, 1991.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646–3614.

NOTICE: Notice is hereby given that, in a letter dated December 10, 1991, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Public Law 93–288, as amended by Public Law 100–707), as follows:

I have determined that the damage in certain areas of the Federated States of Micronesia, resulting from Typhoon Yuri on November 25–29, 1991, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the Federated States of Micronesia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Richard A. Buck of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Federated States of Micronesia to have been affected adversely by this declared major disaster:

The Island of Pohnpei, Mwoakilloa Atoll, and Pingelap Atoll for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 91–30067 Filed 12–16–91; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed; Compagnie Generale Maritime, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202–011102–016.

Title: U.S. Atlantic & Gulf/Western Mediterranean Rate Agreement.

Parties: Compagnie Generale Maritime, Compania Transatlantica Espanola, S.A., Evergreen Marine Corporation (Taiwan), Ltd., Italia di Navigazione, S.p.A., Lykes Lines, Nedlloyd Lines, P & O Containers Limited, Sea-Land Service, Inc., Zim Israel Navigation Company, Ltd.

Synopsis: The proposed amendment would revise article 5.1(b) of the Agreement Authority to permit the members to discuss and agree upon matters pertaining to open tariff items. Adherence to any such agreement is voluntary.

Agreement No.: 217–011360.

Title: Space Charter Agreement between Concorde Line and Network Shipping, Ltd.

Parties: Concorde Line, Network Shipping Ltd.

Synopsis: The proposed Agreement would permit the parties to charter space aboard one another's vessels in the trade between ports in Honduras, Guatemala, Nicaragua and El Salvador and U.S. Atlantic and Gulf ports and inland U.S. points via such ports.

Agreement No.: 217–011361.

Title: Space Charter Agreement between Concorde Line and Central America Shippers S.A.

Parties: Concorde Line, Central America Shippers S.A.

Synopsis: The proposed Agreement would permit the parties to charter space aboard one another's vessels in the trade between ports in Honduras, Guatemala, Nicaragua and El Salvador and U.S. Atlantic and Gulf ports and inland U.S. points via such ports.

Dated: December 12, 1991.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 91–30094 Filed 12–16–91; 8:45 am]

BILLING CODE 6730–01–M

Agreement(s) Filed; Port Authority of New York and New Jersey, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC. Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–200005–006.

Title: Port Authority of New York and New Jersey/Maher Terminals Lease Agreement.

Parties: Port Authority of New York and New Jersey Maher Terminals, Inc.

Synopsis: The Agreement, filed December 4, 1991, provides for the modification of lease rental terms. The Agreement covers the period from the effective date of the agreement through September 30, 2000.

Agreement No.: 224–200493–001.

Title: Port Authority of New York and New Jersey/Maher Terminals, Inc. Agreement.

Parties: Port Authority of New York and New Jersey Maher Terminals, Inc.

Synopsis: The Agreement, filed December 4, 1991, provides for an extension of Permit No. PEP–44 for a period expiring June 30, 1992 and an increase in additional space to be used for the receipt, distribution and transshipment of waterborne freight.

Agreement No.: 224–200598.

Title: Los Angeles Harbor Department/California Cartage Co., Inc. Lease Agreement.

Parties: Los Angeles Harbor Department California Cartage Company, Inc.

Synopsis: The Agreement, filed December 4, 1991, provides California Cartage Company with a five-year lease covering warehouse 13, 17 and Bay 5 of warehouse 16 plus land for container storage, container repair, truck parking, truck scales and an office site. The Agreement covers operation and maintenance of warehouses, container freight stations, Custom Bonded warehouses, cargo and merchandise storage, container storage and repair and purposes incidental thereto.

Dated: December 11, 1991.

By Order of the Federal Maritime Commission.

[FR Doc. 91–29995 Filed 12–16–91; 8:45 am]

BILLING CODE 6730–01–M

[Docket No. 91–57]

Philadelphia Regional Port Authority et al. v. USA-North Europe Rate Agreement et al.; Filing of Complaint and Assignment

Notice is given that a complaint filed by Philadelphia Regional Port Authority; Custom House Brokers Association; Trans Freight Systems, Inc.; S.T.S. International, Inc.; Holt Cargo Systems, Inc.; Marty's Express, Inc.; Delaware River Port Authority; Pennsylvania Liquor Control Board; International Longshoremen's Association; and John A. Steer Company (collectively designated "Complainants") against USA-North Europe Rate Agreement; North Europe-USA Rate Agreement; Atlantic Container Line; P&O Container's Limited; Sea-Land Service, Inc.; A.P. Moller-Maersk Line; Compagnie Generale Maritime; Nedlloyd Lijnen; and Hapag-Lloyd A.G. (collectively designated "Respondents") was served December 11, 1991. Complainants allege that Respondents have violated sections 6(g) and 10 (b)(11), (b)(12), (c)(1) and (c)(2) of the Shipping Act of 1984, 46 U.S.C. app. 1705(g) and 1705 (b)(11), (b)(12), (c)(1) and (c)(2), by filing conference tariff changes eliminating alternate port service to Philadelphia effective January 1, 1992, while providing unfair advantage to neighboring ports.

This proceeding has been assigned to Administrative Law Judge Norman D. Kline ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by December 11, 1992, and the final decision of the Commission shall be issued by April 12, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 91–30052 Filed 12–16–91; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Barclays PLC; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the

proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 7, 1992.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Barclays PLC, London, England, Barclays Bank PLC, London, England, Bay Banks, Inc., Boston, Massachusetts, Chemical Banking Corporation, New York, New York, Manufacturers Hanover Corporation, New York, New York, National Westminster Bank PLC, London, England, NatWest Holdings, Inc., New York, New York, Northeast Bancorp, Inc., New Haven, Connecticut, The Bank of New York Company, Inc., New York, New York, The Chase Manhattan Corporation, New York, New York, and HSBC Holdings, PLC, London, England, The Hongkong and Shanghai Banking Corporation Limited, Hong Kong, B.C.C., Kellett NV, Curacao, Netherlands Antilles, HSBC Holdings BV, Amsterdam, The Netherlands, and Marine Midland Banks, Inc., Buffalo, New York; to expand the activities of The New York Switch Corporation, Fort Lee, New Jersey, and thereby engage in certain data processing activities permitted pursuant to § 225.25(b)(7) of the Board's Regulation Y, including the ownership, installation, operation and maintenance of automated teller machines and scrip terminals at supermarket and other merchant locations in the states of Connecticut, Pennsylvania and Vermont.

Board of Governors of the Federal Reserve System, December 11, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-30040 Filed 12-16-91; 8:45 am]

BILLING CODE 6210-01-F

Lanier Bankshares, Inc.; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 7, 1992.

A. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. Lanier Bankshares, Inc., Gainesville, Georgia; to engage *de novo* through its subsidiary, Lanier Data Corporation, Gainesville, Georgia, in data processing and transmission services pursuant to § 225.25(b)(7).

Board of Governors of the Federal Reserve System, Decmeber 11, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-30041 Filed 12-16-91; 8:45 am]

BILLING CODE 6210-01-F

New Independent Bancshares, Inc., et al.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than January 7, 1992.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. New Independent Bancshares, Inc., New Washington, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of The New Washington State Bank, New Washington, Indiana.

Board of Governors of the Federal Reserve System, December 11, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-30042 Filed 12-16-91; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of funds for fiscal year 1992 for awarding grants to support only phase 2 and phase 3 clinical trials on safety and effectiveness of orphan products in rare diseases and conditions (i.e., one affecting fewer than 200,000 people in the United States). FDA intends to award no more than $800,000 for up to four grants of up to $200,000 each in direct costs per annum for up to 2 years. Applications exceeding this limit will be considered nonresponsive and will be returned. Applicants may submit an application under this announcement or under RFA–FDA–OP–92–2, but may not submit under both for the same product and indication. This notice is subject to the availability of FY–92 funds.

DATES: The closing date for submission of applications is February 18, 1992.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, State Contracts and Assistance Agreements Branch (HFA–520), Food and Drug Administration, Park Bldg., Rm. 3–20, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

NOTE: Applications hand-carried or commercially delivered should be addressed to Park Bldg., Rm. 3–20, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Robert L. Robins, address above.

Regarding the programmatic aspects of this notice: Carol A. Wetmore, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, room 8–73, Rockville, MD 20857, 301–443–4903.

SUPPLEMENTARY INFORMATION: FDA will support the clinical studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service urges applicants to submit work plans that address specific objectives of Healthy People 2000. Potential applicants may obtain a copy of Healthy People 2000 (Full Report; stock # 017–001–00474–0) or Healthy People 2000 (Summary Report; stock # 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–783–3238.

I. Background

The Office of Orphan Products Development (OPD) was established to identify and facilitate the availability of orphan products. In the OPD grants program, orphan products are defined as drugs, biologics, medical devices, and foods for medical purposes which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States).

One way to make orphan products available is to support clinical research to determine whether the products are safe and effective. FDA has allocated funds to support such research since fiscal year 1983. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations promulgated thereunder. The grants are funded under the legislative authority of section 301 of the Public Health Service Act.

II. Research Goal and Objectives

A. Clinical Studies

The goal of FDA's OPD grants program is to encourage clinical development of products for use in rare diseases or conditions. In furtherance of this goal, FDA provides grants to conduct pivotal clinical studies intended to provide data acceptable to the agency which will either result in or substantially contribute to approval of these products. Applicants should keep this goal in mind and must include an explanation in the "Specific Aims" section of the application of how their proposed study will either facilitate product approval or provide essential data needed for product development. The application will be considered nonresponsive without this explanation in the "Specific Aims" section and will be returned.

Except for medical foods that do not require premarket approval, FDA will only consider awarding grants to support clinical studies for determining whether the products are safe and effective for premarket approval under the act (21 U.S.C. 301 *et seq.*) or under section 351 of the Public Health Service Act (42 U.S.C. 262). In most cases, preliminary clinical research suggesting effectiveness and relative safety will already be available.

Studies submitted in response to this announcement must be continuing in phase 2 or phase 3 of investigation under an existing investigational new drug application (IND) or investigational device exemption (IDE). The IND/IDE number and the date it was submitted must appear on the face page of the application with the title of the project. Phase 2 trials include controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication in patients with the disease or condition and to determine the common or short-term side effects and risks associated with the drug. Phase 3 trials gather additional information about effectiveness and safety that is necessary to evaluate the overall benefit-risk relationship of the drug and necessary to provide an adequate basis for physician labeling. Phase 1 studies will not be considered under this announcement. (See announcement RFA–FDA–OP–92–2.)

Applications should propose a single discrete clinical trial (one therapy for one indication). The applicant must provide supporting evidence that sufficient quantity of the product to be investigated is available to the applicant in the form needed for the clinical trial. (A letter from the supplier as an appendix will be acceptable.) The applicant must also provide supporting evidence that the patient population has been surveyed and that there is reasonable assurance that the necessary number of eligible patients are available for the study. (This information should be included in the "Specific Aims" section of the application.)

The typical study that FDA will consider for support may involve up to several dozen subjects, will be well-controlled, and will be designed to provide substantial evidence of the safety and effectiveness of the product.

FDA's standards for adequate and well-controlled studies should be followed. In designing a well-controlled study, the investigator should especially keep in mind that historical controls or use of the subjects as their own control is generally less desirable and reliable than active control or placebo controls. The applicant's proposal should provide a rationale for use of the control method chosen to satisfy considerations of scientific quality.

B. Significance

All investigators submitting a grant application for a proposed orphan use in response to this request for applications must include in the "Specific Aims" section of the "Research Plan" of their application, an explanation of why the product meets the objectives of the OPD grants program and why the product to be studied is an orphan product as described in the "Background" section of this notice. If this explanation is not included in the "Specific Aims" section, the application will be considered nonresponsive and will be returned.

C. Statistical Support

Statistical expertise is helpful in the planning, design, execution, and analysis of clinical investigations and

clinical pharmacology to ensure the validity of estimates of safety and efficacy obtained from human studies. Applicants are expected to provide a statistical justification for the number of patients chosen for the trial based on the proposed outcome measures. Applicants should also document the appropriateness of the statistical procedures to be used in analysis of the results.

D. Journal Reference

Published reports are necessary and often critical for the review process and help to support the investigator's research intent. Applicants may include copies of reprints of relevant references for FDA review. This should include favorable as well as unfavorable reports. Applicants should follow "Specific Instructions—Section 3, Appendix" of the application kit (six collated sets). The application may be returned if the applicant fails to observe the Appendix size limitations.

III. HUMAN SUBJECT PROTECTION AND INFORMED CONSENT

A. Research Involving Human Subjects

Applicants should carefully review the section on human subjects on pages 4 and 5 of the instructions in the application kit. The "Specific Instructions—Section 1, Item 4, Human Subjects," on pages 12 and 13 of the application kit should also be carefully reviewed for the certification of institutional review board (IRB) approval requirements. The goal should be to include enough information on the protection of human subjects in a sufficiently clear fashion so reviewers will have adequate material to make a complete review.

B. Informed Consent

Consent and/or assent forms and any additional information to be given to a subject should accompany the Grant Application Form PHS 398 (Rev. 10/88) or PHS 5161 for State and local governments. Information that is given to the subject or the subject's representative shall be in language that the subject or his or her representative can understand. No informed consent, whether oral or written, may include any language through which the subject or the subject's representative is made to waive any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability.

If a study involves both adults and children, separate consent forms must be provided for the adults and the parents or guardians of the children.

C. Elements of Informed Consent

The elements of informed consent are as stated in the regulations at 45 CFR 46.116 and 21 CFR 50.25 as follows:

1. Basic elements of informed consent

In seeking informed consent, the following information shall be provided to each subject.

(a) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(b) A description of any reasonably foreseeable risks or discomforts to the subject.

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(e) A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that FDA may inspect the records.

(f) For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research related injury to the subject.

(h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each subject.

(a) A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(c) Any costs to the subject that may result from participation in the research.

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(f) The approximate number of subjects involved in the study. The informed consent requirements are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

Nothing in the notice is intended to limit the authority of a physician to provide emergency medical care to the extent that a physician is permitted to do so under applicable Federal, State, or local law.

IV. Reporting Requirements

A program progress report and a Financial Status Report (FSR) (SF–269) are required. An original FSR and two copies of this report shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file the Financial Status Report (SF–269) in a timely fashion will be grounds for suspension or termination of the grant.

A final program progress report, Financial Status Report (SF–269), and Invention Statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Program monitoring of grantees may be conducted on an ongoing basis and written reports will be done at least quarterly by the project officer. The monitoring may be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the grantee organization. The results of these reports will be duly recorded in the official grant file and may be available to the grantee upon request.

V. Mechanism of Support

A. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of the Public

Health Service, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations promulgated under Executive Order 12372 do not apply to this program.

All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 507, 512, and 515 of the act (21 U.S.C. 355, 357, 360b, and 360e), section 351 of the Public Health Service Act, and regulations promulgated under any of these sections.

B. Eligibility

These grants are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must exclude fees or profit from their request for support.

C. Length of Support

The length of the study will depend upon the nature of the study. For those studies with an expected duration of more than 1 year, a second year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year; and (2) the availability of Federal fiscal year appropriations.

D Funding Plan

The number of awards to be made will depend on the quality of the applications received and the availability of Federal funds to support the projects. No more than four awards will be made.

Resources for this program are limited. Therefore, should FDA approve two or more applications which propose duplicative or very similar studies, FDA will support only the study with the best score.

VI. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this request for applications will first be reviewed by grants management and program staff for responsiveness to this request for applications. If applications are found to be nonresponsive, they will be returned to the applicant. Applicants may submit either an application under this announcement or under RFA–FDA–OP–92–2, but may not submit under both.

Responsive applications will be reviewed and evaluated for scientific and technical merit by experts in the subject field of the specific application. This review will take the form of either competitive review panels or field readers. To ensure fairness, the score by both types of reviews (panels and readers) will be combined into one rank order for the entire competition. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence of the recommendations made by the first level reviewers with funding decisions made by the Commissioner, Food and Drug Administration.

B. Responsiveness Review Criteria

Before the applications are sent out for the first level review, they will be evaluated by program and grants management staff for responsiveness according to the following criteria:

1. Whether the application proposes a single discrete clinical trial, conducted in phase 2 or phase 3 of study, with the IND/IDE number noted on the face page of the application to determine safety and efficacy of an orphan product. (Phase 1 studies will not be considered under this announcement; see FRA–FDA–OP–92–2.);

2. Whether a brief statement has been included in the "Research Plan, Section A," under "Specific Aims" as to why the product is appropriate to the objectives of the OPD grants program;

3. Whether an explanation has been included in the "Research Plan, Section A," under "Specific Aims" as to how the proposed study will either facilitate product approval or provide essential data needed for product development;

4. Whether there is supporting evidence that a sufficient quantity of the product is available to the applicant in the form needed for the investigation.

5. Whether the product is subject to FDA review prior to marketing (Medical foods will be exempt when they are not subject to premarket approval requirements.); and

6. Whether the requested budget is within the limits (up to $200,000) as stated in this request for applications.

Applications considered nonresponsive to the review criteria will be returned to the applicant.

C. Scientific/Technical Review Criteria

For the first level of review, the scientific and technical merit criteria are:

1. The soundness of the rationale for the proposed study;

2. The appropriateness and quality of the study design;

3. The adequacy of the evidence that the proposed number of eligible subjects can be recruited;

4. The qualifications of the investigator and support staff and resources available to them;

5. The adequacy of the justification for the request for financial support;

6. The adequacy of plans for complying with regulations for protection of human subjects; and

7. The ability of the applicant to complete the proposed study within its budget and within time limitations stated in this request for applications.

VII. Submission Requirements

The original and six copies of the completed Grant Application Form PHS 398 (Rev. 10/88) or the original and two copies of the PHS 5161 for State and local governments, with copies of the appendix for each of the copies, should be delivered to Robert L. Robins (address above). No supplemental material will be accepted after the closing date. (Evidence of final IRB approval will be accepted for the file after the closing date, but it will not be sent out to the first level reviewers.)

The outside of the mailing package and item #2 of the application face page should be labeled, "Response to FRA–FDA–OP–92–1."

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established closing date.

Applications will be considered received on time if sent on or before the closing date(s) as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant.

Note: Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on the method, applicants should check with their local post office.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 10/88). All "General Instructions" and "Specific Instructions' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the Division of Research Grants, the National Institutes of Health. Applications from State and local governments should be submitted on Form PHS 5161. The face page of the application must reflect the request for applications number RFA–FDA–OP–92–1. An IND/IDE number and the date of submission must appear on the face

page of the application with the title of the project. Applicants may submit an application under this announcement or under RFA–FDA–OP–2, but they may not submit under both for the same product and indication. The title of the proposed study must include the name of the product and the disease/disorder to be studied along with the IND/IDE number and the submission date of the IND/IDE. Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: November 15, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91–30044 Filed 12–16–91; 8:45 am]

BILLING CODE 4160–01–M

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of funds for fiscal year 1992 for awarding grants to support any phases of clinical trials on safety and effectiveness of orphan products in rare diseases and conditions (usually affecting a U.S. population of less than 200,000). FDA intends to award approximately $3 million for 15 to 20 grants of up to $100,000 each in direct costs per annum for up to 3 years. Applications exceeding this limit will be considered nonresponsive and will be returned. Applicants may submit an application under this announcement or under RFA–FDA–OP–92–1 (phase two and three only), but may not submit for the same product and indication under both announcements. This notice is subject to the availability of FY–92 funds.

DATES: The closing date for submission of applications is February 18, 1992.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, State Contracts and Assistance Agreements Branch (HFA–520), Food and Drug Administration, Park Bldg., rm. 3–20, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

Note: Applications hand-carried or commercially delivered should be addressed to Park Bldg., rm. 3–20, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Robert L. Robins, address above.

Regarding the programmatic aspects of this notice: Carol A. Wetmore, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 8–73, Rockville, MD 20857, 301–443–4903.

SUPPLEMENTARY INFORMATION: FDA will support the clinical studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service urges applicants to submit work plans that address specific objectives of Healthy People 2000. Potential applicants may obtain a copy of Healthy People 2000 (Full Report; stock #017–001–00474–0) or Healthy People 2000 (Summary Report; stock #017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–783–3238.

I. Background

The Office of Orphan Products Development (OPD) was established to identify and facilitate the availability of orphan products. In the OPD grants program, orphan products are defined as drugs, biologics, medical devices, and foods for medical purposes which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States).

One way to make orphan products available is to support clinical research to determine whether the products are safe and effective. FDA has allocated funds to support such research since fiscal year 1983. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations promulgated thereunder. The grants are funded under the legislative authority of section 301 of the Public Health Service Act.

II. Research Goal and Objectives

A. Clinical Studies

The goal of FDA's OPD grants program is to encourage clinical development of products for use in rare diseases or conditions. In furtherance of this goal, FDA provides grants to conduct pivotal clinical studies intended to provide data acceptable to the agency which will either result in or substantially contribute to approval of these products. Applicants should keep this goal in mind and must include an explanation in the "Specific Aims" section of the application of how their proposed study will either facilitate product approval or provide essential data needed for product development. The application will be considered nonresponsive without this explanation in the "Specific Aims" section and will be returned.

Except for medical foods that do not require premarket approval, FDA will only consider awarding grants to support clinical studies for determining whether the products are safe and effective for premarket approval under the act (21 U.S.C. 301 *et seq.*) or under section 351 of the Public Health Service Act (42 U.S.C. 262). In most cases, preliminary clinical research suggesting effectiveness and relative safety will already be available.

Applications should propose a single discrete clinical trial (one therapy for one indication). The applicant must provide supporting evidence that sufficient quantity of the product to be investigated is available to the applicant in the form needed for the clinical trial. (A letter from the supplier as an appendix will be acceptable.) The applicant must also provide supporting evidence that the patient population has been surveyed and that there is reasonable assurance that the necessary number of eligible patients are available for the study. (This information should be included in the "Specific Aims" section of the application.)

The typical study that FDA will consider for support may involve up to several dozen subjects, will be well-controlled, and will be designed to

provide substantial evidence of the safety and effectiveness of the product.

FDA's standards for adequate and well-controlled studies should be followed. In designing a well-controlled study, the investigator should especially keep in mind that historical controls or use of the subjects as their own control is generally less desirable and reliable than active control or placebo controls. The applicant's proposal should provide a rationale for use of the control method chosen to satisfy considerations of scientific quality.

B. Significance

All investigators submitting a grant application for a proposed orphan use in response to this request for applications must include, in the "Specific Aims" section of the "Research Plan" of their application, an explanation of why the product meets the objectives of the OPD grants program and why the product to be studied is an orphan product as described in the "Background" section of this notice. If this explanation is not included in the "Specific Aims" section, the application will be considered nonresponsive and will be returned.

C. Statistical Support

Statistical expertise is helpful in the planning, design, execution, and analysis of clinical investigations and clinical pharmacology to ensure the validity of estimates of safety and efficacy obtained from human studies. Applicants are expected to provide a statistical justification for the number of patients chosen for the trial based on the proposed outcome measures. Applicants should also document the appropriateness of the statistical procedures to be used in analysis of the results.

D. Journal Reference

Published reports are necessary and often critical for the review process and help to support the investigator's research intent. Applicants may include copies of reprints of relevant references for FDA review. This should include favorable as well as unfavorable reports. Applicants should follow "Specific Instructions—Section 3, Appendix" of the application kit (six collated sets). The application may be returned if the applicant fails to observe the Appendix size limitations.

III. Human Subject Protection and Informed Consent

A. Research Involving Human Subjects

Applicants should carefully review the section on human subjects on pages 4 and 5 of the instructions in the application kit. The "Specific Instructions—Section 1, Item 4, Human Subjects," on pages 12 and 13 of the application kit should also be carefully reviewed for the certification of institutional review board (IRB) approval requirements. The goal should be to include enough information on the protection of human subjects in a sufficiently clear fashion so reviewers will have adequate material to make a complete review.

B. Informed Consent

Consent and/or assent forms and any additional information to be given to a subject should accompany the Grant Application Form PHS 398 (Rev. 10/88) or PHS 5161 for State and local governments. Information that is given to the subject or the subject's representative shall be in language that the subject or his or her representative can understand. No informed consent, whether oral or written, may include any language through which the subject or the subject's representative is made to waive any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability.

If a study involves both adults and children, separate consent forms must be provided for the adults and the parents or guardians of the children.

C. Elements of Informed Consent

The elements of informed consent are as stated in the regulations at 45 CFR 46.116 and 21 CFR 50.25 as follows:

1. *Basic Elements of Informed Consent*

In seeking informed consent, the following information shall be provided to each subject.

(a) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(b) A description of any reasonably foreseeable risks or discomforts to the subject.

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(e) A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that FDA may inspect the records.

(f) For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject.

(h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. *Additional Elements of Informed Consent*

When appropriate, one or more of the following elements of information shall also be provided to each subject.

(a) A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(c) Any costs to the subject that may result from participation in the research.

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(f) The approximate number of subjects involved in the study.

The informed consent requirements are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

Nothing in the notice is intended to limit the authority of a physician to provide emergency medical care to the extent that a physician is permitted to do so under applicable Federal, State, or local law.

IV. Reporting Requirements

A program progress report and a Financial Status Report (FSR) (SF–269)

are required. An original FSR and two copies of this report shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file the Financial Status Report (SF-269) on time will be grounds for suspension or termination of the grant.

A final program progress report, Financial Status Report (SF-269), and Invention Statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Program monitoring of grantees may be conducted on an ongoing basis and written reports will be done at least quarterly by the project officer. The monitoring may be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the grantee organization. The results of these reports will be duly recorded in the official grant file and may be available to the grantee upon request.

V. Mechanism of Support

A. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of the Public Health Service, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations promulgated under Executive Order 12372 do not apply to this program.

All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 507, 512, and 515 of the act (21 U.S.C. 355, 357, 360b, and 360e), section 351 of the Public Health Service Act, and regulations promulgated under any of these sections.

B. Eligibility

These grants are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must exclude fees or profit from their request for support.

C. Length of Support

The length of the study will depend upon the nature of the study. For those studies with an expected duration of more than 1 year, a second and third year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year; and (2) the availability of Federal fiscal year appropriations.

D. Funding Plan

The number of studies funded will depend on the quality of the applications received and the availability of Federal funds to support the projects. Before an award will be made, acknowledgement of the receipt of an investigational new drug (IND) application or an investigational device (IDE) exemption must be submitted.

Resources for this program are limited. Therefore, should FDA approve two or more applications which propose duplicative or very similar studies, FDA will support only the study with the best score.

VI. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this request for applications will first be reviewed by grants management and program staff for responsiveness to this request for applications. If applications are found to be nonresponsive, they will be returned to the applicant. Applicants may submit either an application under this announcement or under RFA-FDA-OP-92-1, but may not submit under both.

Responsive applications will be reviewed and evaluated for scientific and technical merit by experts in the subject field of the specific application. This review will take the form of either competitive review panels or field readers. To ensure fairness, the score by both types of reviews (panels and readers) will be combined into one rank order for the entire competition. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence of the recommendations made by the first level reviewers with funding decisions made by the Commissioner, Food and Drug Administration.

B. Responsiveness Review Criteria

Before the applications are sent out for the first level review, they will be evaluated by program and grants management staff for responsiveness according to the following criteria:

1. Whether the application proposes a single discrete clinical trial to determine safety and efficacy of an orphan product.

2. Whether a brief statement has been included in the "Research Plan, Section A," under "Specific Aims" as to why the product is appropriate to the objectives of the OPD grants program;

3. Whether an explanation has been included in the "Research Plan, Section A," under "Specific Aims" as to how the proposed study will either facilitate product approval or provide essential data needed for product development;

4. Whether there is supporting evidence that a sufficient quantity of the product is available to the applicant in the form needed for the investigation;

5. Whether the product is subject to FDA review prior to marketing. (Medical foods will be exempt when they are not subject to premarket approval requirements.); and

6. Whether the requested budget is within the limits (up to $100,000) as stated in this request for applications.

Applications considered nonresponsive will be returned to the applicant.

C. Scientific/Technical Review Criteria

For the first level of review, the scientific and technical merit criteria are:

1. The soundness of the rationale for the proposed study;

2. The appropriateness and quality of the study design;

3. The adequacy of the evidence that the proposed number of eligible subjects can be recruited;

4. The qualifications of the investigator and support staff and resources available to them;

5. The adequacy of the justification for the request for financial support;

6. The adequacy of plans for complying with regulations for protection of human subjects; and

7. The ability of the applicant to complete the proposed study within its budget and within time limitations stated in this request for applications.

VII. Submission Requirements

The original and six copies of the completed Grant Application Form PHS 398 (Rev. 10/88) or the original and two copies of the PHS 5161 for State and local governments, with copies of the appendix for each of the copies, should be delivered to Robert L. Robins (address above). No supplemental material will be accepted after the closing date. (Evidence of final IRB approval will be accepted for the file after the closing date, but it will not be sent out to the first level reviewers.)

The outside of the mailing package and item #2 of the application face page should be labeled, "Response to RFA-FDA-OP-92-2."

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established closing date.

Applications will be considered received on time if sent on or before the closing date(s) as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant.

Note: Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before replying on this method, applicants should check with their local post office.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 10/88). All "General Instructions" and "Specific Instructions" in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the Division of Research Grants, the National Institutes of Health. Applications from State and local governments should be submitted on Form PHS 5161. The face page of the application must reflect the request for applications number RFA–FDA–OP–92–2. Applicants may submit an application under this announcement or under RFA–FDA–OP–92–1, but they may not submit under both announcements for the same product and indication. The title of the proposed study must include the name of the product and the disease/disorder to be studied. Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: November 15, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91–30043 Filed 12–16–91; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 91N–0498]

Superpharm Corp., et al.; Withdrawal of Approval of Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 25 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: January 16, 1991.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–295–8038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
70–008	Metronidazole Tablets U.S.P., 250 milligrams (mg).	Superpharm Corp., 1769 Fifth Ave., Bayshore, NY 11706.
70–009	Metronidazole Tablets U.S.P., 500 mg.	Do.
71–750	Droperidol Injection U.S.P., 2.5 mg/milliliter (mL) (2 mL and 5 mL Ampules).	Smith & Nephew Solopak, 1845 Tonne Rd., Elk Grove Village, IL 60007–5125.
80–293	Delta-Dome (prednisone) Tablets, 5 mg.	Miles, Inc., 400 Morgan Lane, West Haven, CT 06516.
80–410	Procaine Hydrochloride Injection U.S.P., 1% and 2%.	Elkins-Sinn, Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08003–4099.
80–972	Vi-Dom-A Capsules (Vitamin A Palmitate Capsules, 50,000 I.U.).	Miles, Inc.
83–381	Antagonate (Chlorpheniramine Maleate) Tablets, 4 mg.	Do.
84–529	Chlorpromazine Hydrochloride Injection U.S.P., 25 mg/mL (vial).	Elkins-Sinn, Inc.
84–626	Lidocaine Hydrochloride Injection U.S.P., 4%.	Do.
85–017	Genapax (gentian violet) Tampons.	Key Pharmaceuticals, Inc., 2000 Galloping Rd., Kenilworth, NJ 07033.
85–131	Lidocanie Hydrochloride Injection U.S.P., 0.5%.	Elkins-Sinn, Inc.
86–357	Heparin Lock Flush Solution, 10 and 500 U.S.P..	International Medication Systems Limited, 1886 Santa Anita Ave., South El Monte, CA 91733.
87–448	Quinidine Gluconate Extended-release Tablets, 324 mg.	Bolar Pharmaceutical Co., Inc., 33 Ralph Ave., P.O. Box 30, Copiague, NY 11726–0030.
88–541	Triprolidine and Psuedoephedrine Hydrochloride Syrup.	Bausch & Lomb, 8500 Hidden River Parkway, Tampa, FL 33637.
88–986	Chlordiazepoxide Hydrochloride Capsules U.S.P., 10 mg.	Superpharm Corp.
88–987	Chlordiazepoxide Hydrochloride Capsules U.S.P., 5 mg.	Do.
88–988	Chlordiazepoxide Hydrochloride Capsules U.S.P., 25 mg.	Do.
89–021	Cyproheptadine Hydrochloride Syrup, 2 mg/5 mL.	Naska Pharmacal Co., Inc., Riverview Rd., P.O. Box 898, Lincolnton, NC 28093.

ANDA No.	Drug	Applicant
89-031	Hydroxyzine Pamoate Capsules U.S.P., 25 mg.	Superpharm Corp.
89-032	Hydroxyzine Pamoate Capsules U.S.P., 50 mg.	Do.
89-033	Hydroxyzine Pamoate Capsules U.S.P., 100 mg.	Do.
89-137	Spironolactone and Hydrochlorothiazide Tablets, 25 mg/25 mg.	Do.
89-704	Hydrocortisone Ointment U.S.P., 1%.	Naska Pharmacal Co., Inc.
89-705	Hydrocortisone Lotion U.S.P., 1%.	Do.
89-706	Hydrocortisone Cream U.S.P., 1%.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82), approval of the abbreviated new drug applications listed above, and all supplements thereto, is hereby withdrawn, effective January 16, 1991.

Dated: December 9, 1991.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 91-30095 Filed 12-16-91; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

[MB-040-N]

Medicaid Program; Model Medicaid Application Form

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice publishes a model Medicaid application form that States have the option of using in full, in part, with modification or not at all. It would be used for noninstitutionalized individuals applying for benefits under title XIX of the Social Security Act who are not receiving cash assistance under the Aid to Families with Dependent Children (AFDC) program, Part A of title IV of the Social Security Act. This notice is published in accordance with section 6506(b) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239), which requires the Secretary to develop a model Medicaid application form for publication in the **Federal Register**.

EFFECTIVE DATE: This notice is effective December 17, 1991.

FOR FURTHER INFORMATION CONTACT: Elliott Weisman (301) 966-4723.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1902 of the Social Security Act (the Act) State agencies administer the Medicaid program in compliance with Federal statutory and regulatory requirements, and in accordance with a State plan approved by HCFA. Individuals qualify for Medicaid on the basis of being members of a category of eligibles, e.g., aged, blind, disabled, pregnant women, or families with dependent children, and on the basis of meeting certain income and resource requirements. In most States, if individuals qualify for cash assistance under the AFDC or SSI programs (or for aid to the aged, blind, or disabled in the Territories), the receipt of cash assistance automatically qualifies them for Medicaid without a separate Medicaid application. Individuals ineligible under AFDC, SSI, or for aid to the aged, blind, or disabled in the Territories, may still qualify for Medicaid. These individuals must file an application with the State.

Section 1902(a)(8) of the Act provides that all individuals wishing to make application for medical assistance under the State Medicaid plan must have the opportunity to do so, and that such assistance must be furnished with reasonable promptness to all eligible individuals. Each State agency designs its own applications for medical assistance and redetermination of eligibility. Our regulations at 42 CFR 435.907 specify that the agency must require a written application from the applicant, an authorized representative or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant. The application must be on a form prescribed by the agency and signed under a penalty of perjury.

Our regulations at 42 CFR 435.905 through 435.909, 436.900, 436.901 and 436.909 specify the rules for application requirements that a State agency must furnish to all applicants and individuals. In addition, the agency must publish in quantity and make available bulletins or pamphlets that explain the rules governing eligibility and appeals in simple and understandable terms.

II. Provisions of This Notice

Section 6506(b)(1) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101-239), enacted December 19, 1989, requires the Secretary to develop not later than December 19, 1990, a model application form for use in applying for Medicaid benefits for individuals who are not receiving cash assistance under the AFDC program, Part A of title IV of the Act, and who are not institutionalized. Use of the model application form is optional; the Secretary is not authorized to require that the form be adopted by a State as part of its State Medicaid plan.

Section 6506(b)(2) of OBRA 89 also requires the Secretary to provide for publication in the **Federal Register** of the model application form and, in addition, to send a copy of the form to each State agency responsible for administering a State Medicaid plan.

To address the legislative mandate, we determined that it would be desirable to base our model on forms actually being used since any information about actual experience with a form would be useful in evaluating its clarity and completeness. We contacted each of our ten regional offices, who, in turn, contacted the States in their areas to secure actual applications in use. These applications were forwarded to us for review. We received approximately 50 non-institutional and non-AFDC application forms from the States. The application forms ranged in length from 4 pages to 34 pages.

In reviewing State application forms, we considered their usefulness as a model by considering them in terms of brevity, clarity and ease of completion. We hoped to find in one application all the necessary criteria: Brief, yet thorough treatment of areas such as income and resources; easily understandable terms that would be clear to either a governmental institution or a layman; and a format that was not difficult to follow. We chose to follow one State application, with modifications primarily in the area of assignment of rights. The final selection was made based on these aforementioned objectives, and on our own working knowledge that, had we attempted to initiate and develop a model based on composites of best practices from among several State examples, it would not have resulted in a more professional manuscript than the document selected as our model.

Although we are publishing the model form, we are not including a set of instructions, for several reasons. First, we believe the information being sought and the subject areas are clear and are not new to States. We believe any State choosing to use part or all of the model

would very likely want to use or adopt its own existing instructions. It is not our objective or purpose to have the States defer their own individual initiatives and totally embrace this model application. Second, the States are being asked to review the model and are free to use it intact or to use any portions they feel would be beneficial to them. Also, any one set of instructions could not encompass the myriad of unique State circumstances and systems. Thus, any instructions we prepare probably would need to be altered. Lastly, States are already well familiar with gathering this information. The purpose of the model application is simply to make available to States another potential avenue of reference, illustrating ways in which information can be collected and arrayed.

This model application is published exclusively for States' consideration. States have the option to adopt part, all or none of the model application, and may make any necessary changes in development of an application as part of the State Medicaid plan. It is not intended to thwart expedited enrollment measures which may be in place for pregnant women, infants and children described in section 1902(1) of the Act whose eligibility is related to the poverty level. In addition, the application can be used as a screening form by a "qualified provider" to determine if a pregnant woman is entitled to a period of presumptive eligibility under section 1920 of the Act. A presumptively eligible pregnant woman can receive coverage for ambulatory prenatal care. The provider's determination is based on preliminary information about income alone and the pregnant woman must appear to meet income eligibility standards. The pregnant woman can be required to provide on the application only preliminary information about her income and not exact information under a penalty of perjury; she can choose, however, to complete the entire application in order to apply for regular Medicaid.

At the time the qualified provider makes a presumptive eligibility determination, the provider must inform the pregnant woman that she must complete a regular Medicaid application form (this one or another one) by the last day of the month following the month of her presumptive determination or her presumptive eligibility will end on that last day. If she applies for regular Medicaid within the deadline, her presumptive status will continue until the agency makes a final Medicaid determination.

The model application outlined below has four positive features. The application—

(1) Is short and direct;

(2) Solicits information in an easily understandable format and progression;

(3) Is easy to both read and understand; and

(4) Can be completed without a need for supplemental instructions.

(A copy of this model application has been forwarded to the director of each State agency responsible for administering the Medicaid program.

Model Medicaid Application Form

BILLING CODE 4120-01-M

BENEFIT PROGRAMS
APPLICATION/REDETERMINATION BASE DOCUMENT

AGENCY USE ONLY		
CASE NUMBER	CATEGORY	DATE REC'D
CASE NUMBER	CATEGORY	DATE REC'D
COUNTY / CITY	WORKER'S NAME	

I. IDENTIFYING INFORMATION
(IF YOU ARE NOT APPLYING FOR YOURSELF BUT ANOTHER PERSON, COMPLETE THE FORM AS IF YOU WERE THAT PERSON)

1. NAME (LAST, FIRST, MIDDLE/MAIDEN)

2. MARITAL STATUS
☐ NEVER MARRIED ☐ MARRIED ☐ SEPARATED ☐ DIVORCED ☐ WIDOWED

3. I RESIDE
☐ ALONE ☐ WITH SPOUSE ☐ WITH CHILDREN ☐ HOME FOR ADULTS ☐ NURSING HOME ☐ OTHER (SPECIFY)

APPLICANT	SPOUSE / PARENT
4. ADDRESS (MAILING)	NAME (LAST, FIRST, MIDDLE/MAIDEN)
	ADDRESS (MAILING)
CITY, STATE, ZIP	CITY, STATE, ZIP
RESIDENCE ADDRESS (IF DIFFERENT) / TELEPHONE	RESIDENCE ADDRESS (IF DIFFERENT) / TELEPHONE
5. DOB	DOB
SSN	SSN
6. ARE YOU A VETERAN? ☐ YES ☐ NO	IS YOUR SPOUSE A VETERAN? ☐ YES ☐ NO
7. IS YOUR SPOUSE A VETERAN? ☐ YES ☐ NO	DO YOU HAVE MEDICARE PART A (HOSPITAL COVERAGE)? ☐ YES ☐ NO
8. IS ANYONE FOR WHOM YOU ARE APPLYING SERIOUSLY ILL, DISABLED, NEARLY BLIND, OR BLIND? ☐ YES ☐ NO	DO YOU HAVE MEDICARE PART B (PHYSICIAN COVERAGE)? ☐ YES ☐ NO

9. HAVE YOU OR ANYONE FOR WHOM YOU ARE APPLYING EVER RECEIVED MEDICAL ASSISTANCE OR ANY OTHER BENEFITS? ☐ YES ☐ NO

WHO	UNDER WHAT NAME	FROM WHICH DEPARTMENT
TYPE OF ASSISTANCE	WHEN	MEDICAID NUMBER (IF APPLICABLE)

10. ARE YOU OR ANYONE FOR WHOM YOU ARE APPLYING NOW RECEIVING OR ELIGIBLE FOR MEDICAL ASSISTANCE, OR ANY OTHER BENEFITS? ☐ YES ☐ NO

WHO	UNDER WHAT NAME	FROM WHICH DEPARTMENT
TYPE OF ASSISTANCE		MEDICAID NUMBER (IF APPLICABLE)

11. DO YOU OR ANYONE FOR WHOM YOU ARE APPLYING HAVE MEDICARE PART A (HOSPITAL COVERAGE)? ☐ YES ☐ NO	IF YES, WHO
12. DO YOU OR ANYONE FOR WHOM YOU ARE APPLYING HAVE MEDICARE PART B (PHYSICIAN COVERAGE)? ☐ YES ☐ NO	IF YES, WHO

13. IS PREMIUM DEDUCTED FROM SOCIAL SECURITY OR RAILROAD RETIREMENT CHECK? ☐ YES ☐ NO

14. IF RECEIVING SOCIAL SECURITY OR RAILROAD RETIREMENT BENEFITS OR MEDICARE, LIST CLAIM NUMBER

15. DO YOU WANT TO TALK WITH A SERVICE WORKER ABOUT ANY NEEDS OR PROBLEMS? ☐ YES ☐ NO

16. IF YOU ARE MARRIED, BUT ARE NOT LIVING WITH YOUR SPOUSE, LIST DATE YOU LAST LIVED TOGETHER DATE

II. RESOURCES

DO YOU OR ANYONE FOR WHOM YOU ARE APPLYING, OR YOUR SPOUSE, HAVE ANY OF THE FOLLOWING:

☐ YES ☐ NO CASH ON HAND	WHO	AMOUNT $	☐ YES ☐ NO STOCKS OR BONDS ?	WHO	AMOUNT $

☐ YES ☐ NO MACHINERY, TOOLS, FARMING OR OTHER EQUIPMENT

TYPE OF EQUIPMENT	WHO	VALUE $

☐ YES ☐ NO A SAVINGS ACCOUNT OR CHECKING ACCOUNT, CREDIT UNION, CHRISTMAS CLUB, TRUST FUND, CERTIFICATE OF DEPOSIT, IRA OR KEOUGH PLAN ?

IN WHOSE NAME(S)	TYPE OF ACCOUNT	WHERE	ACCOUNT NUMBER	AMOUNT $
IN WHOSE NAME(S)	TYPE OF ACCOUNT	WHERE	ACCOUNT NUMBER	AMOUNT $

☐ YES ☐ NO DO YOU, YOUR SPOUSE, OR ANYONE FOR WHOM YOU ARE APPLYING HAVE PART OR FULL OWNERSHIP OR LIFE INTEREST IN ANY REAL PROPERTY (HOUSE, LAND, BUILDINGS) WHETHER PURCHASED OR INHERITED ?

3. ☐ YES ☐ NO ARE YOU, YOUR SPOUSE, OR ANYONE FOR WHOM YOU ARE APPLYING BUYING ANY REAL PROPERTY NOW ?

IF YOU OWN OR ARE BUYING PROPERTY, LIST:

NAME(S) OF OWNER(S)	NUMBER OF ACRES	VALUE $

WHERE LOCATED	TYPE OF PROPERTY ☐ HOME ☐ HOME AND LAND ☐ OTHER BUILDINGS AND/OR LAND

4. LIST THE HOSPITAL OR MEDICAL INSURANCE (OTHER THAN MEDICARE) OF ANYONE FOR WHOM YOU ARE APPLYING, INCLUDING ANY INSURANCE AVAILABLE TO YOU THROUGH EMPLOYMENT, BLUE CROSS/BLUE SHIELD, CHAMPUS, CHAMPVA, PUBLIC HEALTH SERVICE,UNION OR PROFESSIONAL OR FRATERNAL, SCHOOL INSURANCE, SPECIAL CANCER POLICIES, FEDERAL EMPLOYEE PROGRAMS AND HEALTH MAINTENANCE ORGANIZATIONS (HMO S) USE ADDITIONAL PAPER IF MORE SPACE IS NEEDED.

NAME AND ADDRESS OF INSURANCE COMPANY OR OTHER COVERAGE	POLICY / GROUP / CONTACT / MILITARY ID NUMBER	COVERAGE BEGIN DATE	TYPE OF POLICY	PREMIUM AMOUNT

III. INCOME

1. LIST THE INFORMATION ON ALL PEOPLE, INCLUDING YOURSELF, LIVING IN THE HOME. ALL THE MONEY IS TO BE LISTED FOR EACH PERSON INCLUDING SELF EMPLOYMENT, INCOME PRODUCING PROPERTY, FARMING, BABYSITTING, SOCIAL SECURITY, SSI, ETC. COMPLETE ITEM 5 BELOW IF A MEMBER OF THE HOUSEHOLD IS WORKING. * SOCIAL SECURITY NUMBER REPORTING OPTIONAL FOR INDIVIDUALS NOT RECEIVING MEDICAID.

NAME (LAST, FIRST, MIDDLE)	SOCIAL SECURITY NUMBER	BIRTHDATE	SEX	RELATIONSHIP TO APPLICANT (WIFE, SON, DAUGHTER, ETC.) IF NOT RELATED ENTER NONE	BIRTHPLACE (CITY, STATE OR COUNTRY OF ORIGIN)	IS THIS PERSON EARNING MONEY		
						YES	NO	GROSS AMOUNT

2. DOES ANYONE WITHIN THE HOUSEHOLD HELP YOU IN PAYING ANY BILLS ? ☐ YES ☐ NO	IS THIS A LOAN? ☐ YES ☐ NO	3. DOES ANYONE OUTSIDE THE HOUSEHOLD HELP YOU IN PAYING ANY BILLS ? ☐ YES ☐ NO	IS THIS A LOAN? ☐ YES ☐ NO
WHO	WHICH BILLS	WHO	WHICH BILLS
HOW OFTEN	AMOUNT $	HOW OFTEN	AMOUNT $

5. COMPLETE THIS SECTION FOR ANY PERSON, INCLUDING CHILDREN, EARNING MONEY (IF MORE THAN TWO ARE WORKING, COMPLETE ADDITIONAL SHEET OF PAPER.)

NAME OF PERSON WORKING	NUMBER OF HOURS PER WEEK	NAME OF PERSON WORKING	NUMBER OF HOURS PER WEEK
WHERE		WHERE	
AMOUNT OF GROSS EARNINGS	AMOUNT OF EARNED INCOME CREDIT	AMOUNT OF GROSS EARNINGS	AMOUNT OF EARNED INCOME CREDIT

II. RESOURCES

2. DO YOU OR ANYONE FOR WHOM YOU ARE APPLYING, OR YOUR SPOUSE, HAVE ANY OF THE FOLLOWING:

☐ YES ☐ NO A CEMETERY PLOT, BURIAL FUND OR PREARRANGED FUNERAL ?

WHO	WHAT	WHERE	VALUE

☐ YES ☐ NO ANY CARS, BOATS, TRUCKS, MOTORCYCLES, CAMPERS, MOBILE HOMES, ETC. ?

OWNER	ITEM	MAKE	MODEL	YEAR	AMOUNT OWED	VALUE
					$	$
					$	$
					$	$

☐ YES ☐ NO LIFE INSURANCE POLICIES WHICH CAN BE CASHED IN BY YOU OR ANYONE FOR WHOM YOU ARE APPLYING (NOT REQUIRED FOR FOOD STAMPS)

NAME OF INSURANCE COMPANY	POLICY NUMBER	INSURED PERSON	FACE VALUE	CASH VALUE	TO WHOM IT IS AVAILABLE
			$	$	
			$	$	
			$	$	

4. LIST THE HOSPITAL OR MEDICAL INSURANCE (OTHER THAN MEDICARE) OF ANYONE FOR WHOM YOU ARE APPLYING, INCLUDING ANY INSURANCE AVAILABLE TO YOU THROUGH EMPLOYMENT, BLUE CROSS/BLUE SHIELD, CHAMPUS, CHAMPVA, PUBLIC HEALTH SERVICE,UNION OR PROFESSIONAL OR FRATERNAL, SCHOOL INSURANCE, SPECIAL CANCER POLICIES, FEDERAL EMPLOYEE PROGRAMS AND HEALTH MAINTENANCE ORGANIZATIONS (HMO'S). USE ADDITIONAL PAPER IF MORE SPACE IS NEEDED.

MAJOR MEDICAL		COVERED INDIVIDUALS	EMPLOYER / PERSON WHO BOUGHT THE POLICY	RELATIONSHIP	BENEFITS
YES	NO				
					☐ HOSPITAL ☐ MEDICAL ☐ OTHER (SPECIFY) ☐ SURGICAL ☐ DENTAL
					☐ HOSPITAL ☐ MEDICAL ☐ OTHER (SPECIFY) ☐ SURGICAL ☐ DENTAL
					☐ HOSPITAL ☐ MEDICAL ☐ OTHER (SPECIFY) ☐ SURGICAL ☐ DENTAL

III. INCOME

LIST THE INFORMATION ON ALL PEOPLE, INCLUDING YOURSELF, LIVING IN THE HOME. ALL THE MONEY IS TO BE LISTED FOR EACH PERSON INCLUDING SELF EMPLOYMENT, INCOME PRODUCING PROPERTY, FARMING, BABYSITTING, SOCIAL SECURITY, SSI, ETC. COMPLETE ITEM 5 BELOW IF A MEMBER OF THE HOUSEHOLD IS WORKING.

RECEIVING UNEMPLOYMENT COMPENSATION			RECEIVING SUPPORT PAYMENTS			RECEIVING SOCIAL SECURITY OR SUPPLEMENTAL SECURITY INCOME			RECEIVING FOOD, CLOTHING, SHELTER CONTRIBUTIONS			RECEIVING ANY OTHER PENSIONS,INCOME OR MONEY FROM ANY SOURCE			
YES	NO	AMOUNT	YES	NO	AMOUNT	YES	NO	AMOUNT	YES	NO	AMOUNT	YES	NO	AMOUNT	SOURCE

4. DO YOU, OR ANYONE FOR WHOM YOU ARE APPLYING, OR YOUR SPOUSE, EXPECT TO RECEIVE ANY MONEY FROM ANY SOURCE?

WHO	FROM WHERE	AMOUNT
		$

6. HAVE YOU OR ANYONE FOR WHOM YOU ARE APPLYING, OR YOUR SPOUSE SOLD, GIVEN AWAY, OR TRANSFERRED ANY REAL OR PERSONAL PROPERTY (BANK ACCOUNTS, MONEY, ETC.) IN THE PAST 30 MONTHS ? ☐ YES ☐ NO

IF YES, WHAT, TO WHOM, WHY, WHEN (DATE) AND WHAT DID YOU RECEIVE IN RETURN ?

IF YES, WHAT WAS THE VALUE OF THE TRANSFERRED REAL OR PERSONAL PROPERTY (BANK ACCOUNTS, MONEY, ETC.) $

ASSIGNMENT OF RIGHTS TO MEDICAL SUPPORT AND THIRD-PARTY PAYMENTS

I. **Statement of Citizenship or Alienage:**

In order to receive non-emergency medical assistance, each applicant for Medicaid must certify, under penalty of perjury, whether he or she is a citizen or national of the United States or is in a satisfactory immigration status. Satisfactory immigration status means that the person is living in the United States legally. Please note: While this declaration may be made by a parent on behalf of a minor child, the declaration must be made separately for each adult applying for assistance.

A. Are you a United States Citizen by birth or naturalization? ☐ YES ☐ NO

If no, are you lawfully admittted for permanent residence in the United States? ☐ YES ☐ NO

If you are lawfully admitted for permanent residence, give the month, day, and year of admission. Date:

If you are not lawfully admitted for permanent residence, please complete the following:

(a) Is the Immigration and Naturalization Service (INS) aware of your presence in the United States? ☐ YES ☐ NO
(If Yes, go to (b). If No, go to next question)

(b) When did you first make your home in the United States? Date:

By signing this application, you are certifying that this statement of your citizenship or alienage is true and correct.

II. **Assignment of Rights to Third Party Payment:**

Medicaid does not pay medical expenses that a third party, such as a private health insurance company, is supposed to pay. All persons applying for Medicaid benefits are required to assign the State Medicaid agency any rights they may have to medical support or other third party payments for medical care. When you sign this application for Medicaid benefits, you are assigning the Medicaid agency all rights to collect or receive any such payments for the time you are on Medicaid.

III. **Cooperation Requirements**:

I understand that by applying for Medicaid benefits, I agree to cooperate with the State Medicaid agency in identifying and providing information to help pursue any third party who may be responsible for providing medical support for me. If I am signing this application on behalf of another person, I agree to cooperate in identifying and obtaining information to pursue any third party who may be responsible for providing medical support for them, including, if necessary, establishing paternity for any children applying for Medicaid benefits. I further understand that there is a special exception to this general rule for low-income pregnant women which exempts them from cooperating in establishing paternity.

I also understand that, if I am eligible to enroll in any insurance or benefit plan offered by my employer or my spouse's employer, I am required to enroll in that plan.

IV. **Change in Status**:

I agree to let the State Medicaid agency _____ know immediately _____ (per 42 CFR 435.916) of any changes in my family or financial situation.

V. **Release of Medical Information**:

I hereby authorize the release to the State Medicaid agency of any information in any medical records pertaining to any services received by me or a member of my family as a benefit under Medicaid.

VI. **Non-discrimination**:

I understand that I have the right to file a complaint if I believe I have been discriminated against because of race, color, national origin, religion, sex, age, handicap or religious belief.

VII. **Privacy Act and Computer Matching Notice:**

I understand that the State Medicaid agency is authorized to request the information on this form. The primary use of this information is to determine eligibility for Medicaid benefits and it is protected by law from disclosure to unauthorized persons or for unauthorized purposes.

Please note: It is possible this information may be used:

1) To determine another person's right to Medicaid benefits, or

2) To comply with Federal laws requiring the release of information from Medicaid records. The information may be matched with the records in other agencies, such as the Social Security Administration, the Internal Revenue Service or the Immigration and Naturalization Service. These matches may be done by computer or on an individual basis.

VIII. **Further help:**

If you need additional forms or have any questions, contact: (name, phone number, address or other identifying information provided by the State agency.)

IX. **Penalties for False Statements:**

I understand that if I give false information, withhold information, or fail to report changes promptly or on purpose, I may be breaking the law and could be prosecuted for perjury, larceny and/or welfare fraud. I further understand that if I complete or assist in completing this form for an applicant/recipient and/or aided or abetted the applicant/recipient to obtain assistance for which he/she is not eligible that I may be breaking the law and could be prosecuted.

X. **CERTIFICATION:**

I HEREBY APPLY FOR MEDICAL ASSISTANCE AND CERTIFY THAT THE STATEMENTS AND ATTACHMENTS ON THIS APPLICATION ARE TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.

Signed: _____ Date: _____

BILLING CODE 4120-01-C

III. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any notice that meets one of the Executive Order 12291 criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, State agencies are not considered to be small entities.

This notice does not require either an impact analysis under Executive Order 12291 or a regulatory flexibility analysis under the RFA since it merely notifies and makes available to State agencies responsible for administering the State Medicaid plan, a model application form as required by section 6506(c) of Pub. L. 101–239.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

IV. Paperwork Burden

This notice does not impose paperwork collection requirements. Consequently, it need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3801 et. seq.).

The notice merely makes available to the States a model Medicaid application form for them to consider using either in full, part, or with modification or not at all. States that make no changes to their forms will experience no change in reporting burden. States that find the model simpler or briefer and adopt the model for their own use would likely experience a reduction in burden.

(Catalog of Federal Domestic Assistance Program No. 93.778 Medical Assistance)

Dated: May 6, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: September 17, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91–30002 Filed 12–16–91; 8:45 am]

BILLING CODE 4120–01–M

Social Security Administration

Supplemental Security Income Modernization Project; Change in Location of a Meeting

AGENCY: Social Security Administration, HHS.

ACTION: Notice of change in location of a meeting.

SUMMARY: Notice is hereby given that the meeting of the Supplemental Security Income (SSI) Modernization Project (the Project) that was to be held at the Social Security Administration Headquarters, 6401 Security Boulevard, Baltimore, MD 21235 on January 9 and 10, 1992 will instead be held at the Social Security Administration's Office of Hearings and Appeals, One Skyline Tower 5107 Leesburg Pike, Falls Church, Virginia 22041. This notice supersedes the notice of this meeting published on November 29, 1991 at 56 FR 61030.

DATES: January 9–10, 1992, 8:30 a.m. to 5 p.m.

ADDRESSES: Social Security Administration Office of Hearings and Appeals, One Skyline Tower, room 1600, 5107 Leesburg Pike, Falls Church, Virginia 22041.

FOR FURTHER INFORMATION CONTACT: SSI Modernization Project Staff, room 300, Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–3571.

SUPPLEMENTARY INFORMATION: The meeting of the SSI Modernization Project will be held at a different location. This notice supersedes the notice of this meeting published on November 29, 1991 at 56 FR 61030.

The Social Security Administration (SSA) is undertaking a comprehensive examination of the SSI program, reviewing its fundamental structure and purpose. The purpose of the Project is to determine if the SSI program is meeting and will continue to meet the needs of the population it is intended to serve in an efficient and caring manner, recognizing the constraints in the current fiscal climate.

The first phase of this Project is intended to create a dialogue that provides a full examination of how well the SSI program serves the needy, aged, blind, and disabled.

To begin this dialogue, the Commissioner has involved 23 people who are experts in the SSI program and/or related public policy areas. The experts include a wide range of representatives of the aged, blind, and disabled from private and nonprofit organizations and Federal and State government as well as former SSA staff. Dr. Arthur S. Flemming, former Secretary of Health, Education and Welfare, will chair the meeting. The purpose of this initial dialogue is to exchange ideas and existing information about the program. This exchange will facilitate the sharing of ideas among attendees' constituencies, including advocacy groups, state and local government and academicians. The outcome will be a more informed public that has an interest in bringing individually produced innovative ideas for change in the SSI program to the Modernization Project.

This is the tenth in a series of meetings that have been held throughout the country. The meeting will be open to the public to the extent that space is available. Please call the Project Staff at 410–965–3571, if you plan to attend.

The experts will review and discuss the public comments that were received on the paper, "Summary of Options Identified by the Public In Connection with the Supplemental Security Income Modernization Project." This document was published in the **Federal Register** on July 31, 1991 (56 FR 36640).

A summary of the meeting will be available at no charge. The transcript of the meeting will be available at cost. Summaries and transcripts may be ordered from the Project Staff. The transcript and all written submissions will become part of the record of these meetings.

Dated: December 11, 1991

Peter Spencer,

Director, SSI Modernization Project Staff.

[FR Doc. 91–30053 Filed 12–16–91; 8:45 am]

BILLING CODE 4190–29–M

[Social Security Ruling SSR 91-8P.]

Evaluation of Human Immunodeficiency Virus Infection

AGENCY: Social Security Administration, HHS.

ACTION: Notice of Social Security Ruling.

SUMMARY: In accordance with 20 CFR 422.406(b)(1), the Commissioner of Social Security gives notice of Social Security Ruling 91–8P. This Policy Interpretation Ruling updates the policy for evaluating human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS), in determining disability based on these impairments under titles II (Federal Old-Age, Survivors, and Disability Insurance Benefits) and XVI (Supplemental Security Income for the Aged, Blind, and Disabled) of the Social Security Act. This Ruling uses the universally accepted term "HIV infection" for the virus that causes AIDS.

This Ruling also states the criteria for identifying HIV infection as a disabling condition for Social Security purposes. It includes the diagnostic criteria necessary, explains the documentation and evaluation of all HIV infection (including AIDS) cases, and the setting of the onset date. The Commissioner also gives notice that Social Security Ruling 86–20 is out of date and is superseded by this Ruling.

EFFECTIVE DATE: December 17, 1991.

FOR FURTHER INFORMATION CONTACT: Joanne K. Castello, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1711.

SUPPLEMENTARY INFORMATION: Although we are not required to do so pursuant to 5 U.S.C. 552(a)(1) and (a)(2), we are publishing this Social Security Ruling in accordance with 20 CFR 422.406(b)(1).

Social Security Rulings make available to the public precedential decisions relating to the Federal old-age, survivors, disability, supplemental security income, and black lung benefits programs. Social Security Rulings may be based on case decisions made at all administrative levels of adjudication, Federal court decisions, Commissioner's decisions, opinions of the Office of the General Counsel, and other policy interpretations of the law and regulations.

Although Social Security Rulings do not have the force and effect of the law or regulations, they are binding on all components of the Social Security Administration, in accordance with 20 CFR 422.406(b)(1), and are to be relied upon as precedents in adjudicating other cases.

If this Social Security Ruling is later superseded, modified, or rescinded, we will publish a notice in the **Federal Register** to that effect.

(Catalog of Federal Domestic Assistance Programs Nos. 93.802 Social Security-Disability Insurance; 93.803 Social Security-Retirement Insurance; 93.805 Social Security-Survivor's Insurance; 93.807 Supplemental Security Income.)

Dated: December 11, 1991.

Gwendolyn S. King,

Commissioner of Social Security.

Policy Interpretation Ruling Titles II and XVI: Evaluation of Human Immunodeficiency Virus Infection

This supersedes Program Policy Statement (PPS) No. 124 (Social Security Ruling (SSR) 86–20), titles II and XVI: Evaluation of Acquired Immune Deficiency Syndrome, Cumulative Edition 1986, p. 87.

Purpose: To update the policy for evaluating human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS), in determining disability based on these impairments under titles II and XVI of the Social Security Act.

Citations: Sections 216(i), 223(d) and 1614(a) of the Social Security Act, as amended; Regulations No. 4, subpart P, §§ 404.1520(d), 404.1525, 404.1526, 404.1578, 404.1590, and appendix 1, parts A and B; Regulations No. 16, subpart I, §§ 416.906, 416.920(d), 416.924(e), 416.925, 416.926, and 416.926a.

Introduction: This Ruling revises and expands the guidelines for evaluating cases involving HIV infection. It reformats the opportunistic infections by type (e.g., viral, fungal, bacterial, protozoan, etc.), thereby making the criteria easier to apply.

It also includes additional criteria to take into account the clinical manifestations and course of the disease in women and children, and to reflect recent data on the correlation of absolute CD4 lymphocyte counts and the percentage of total lymphocytes. It also realigns and adds certain manifestations of HIV infection which when paired with functional restrictions result in listing-level severity.

Policy Interpretation: This Ruling states the guidelines for identifying HIV infection as a disabling condition for Social Security purposes. It includes the diagnostic criteria necessary, explains the documentation and evaluation of all HIV infection (including AIDS) cases, and the setting of the onset date.

HIV Infection—General

HIV infection is caused by a specific retrovirus and is characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions.

The criteria in this Ruling include severe HIV-associated conditions that equal the severity of the listings. However, the criteria listed do not describe the full spectrum of diseases or conditions manifested by HIV-infected individuals. When other diseases or conditions are documented, it is necessary to determine whether the other diseases or conditions carry a level of severity equivalent to the HIV criteria specified in this Ruling, or to any listing.

Under the sequential evaluation process, if the medical evidence shows that a person meets the listing criteria (or, as determined by a program physician, has other infections or diseases which are equivalent in severity to the listings), is not working and meets the other nonmedical requirements for entitlement, he or she will be determined to be disabled.

If the person has manifestations of HIV infection that are not specifically included in or equivalent in severity to the specific criteria, then we again evaluate all of his or her signs, symptoms, and laboratory findings to determine the person's capacity to engage in substantial gainful activity (or, in the case of a child, to perform age-appropriate activities).

For adults, we assess their residual functional capacity and, based on that assessment, determine whether the claimant retains the capacity to perform past relevant work, or, if not, whether the claimant retains the capacity to perform any other work considering his or her age, education, and work experience.

For children, we individually assess their ability to function to determine whether there is a substantial reduction in their ability to function independently, appropriately and effectively in an age-appropriate manner.

Documentation of HIV Infection in Adults

The medical file should be documented by the findings of a thorough history and physical examination. The onset and nature of signs and symptoms should be specifically and clearly described. Attempts should be made to quantify the extent and severity of all signs and symptoms. The variability or intensity of

signs, symptoms, and laboratory findings over time should also be indicated.

The medical evidence should include documentation of HIV infection and specific laboratory evidence of an opportunistic disease, cancer, or other condition. The extent of immune depression correlates with the absolute number or percentage of CD4 (T4) lymphocytes. In general, when the CD4 count is 200 per mm^3 or less (14 percent or less), the susceptibility to opportunistic disease is considerably increased. In obtaining information regarding HIV antibody or viral testing, requirements of State and local laws governing the release of information must be met.

Laboratory evidence of HIV infection includes:

1. A serum specimen that contains HIV antibodies, detected by a screening test (e.g., ELISA) and confirmed by a more definitive test (e.g., Western blot, immunofluorescence assay), or

2. A serum specimen that contains HIV antigen, or

3. A lymphocyte culture, positive for HIV, confirmed by a specific test for the antigen (not just detection of reverse transcriptase), or

4. Other test(s) believed to be highly specific for detection of HIV (e.g., polymerase chain reaction (PCR)).

When the above tests are not part of the medical evidence in the file, a diagnosis of HIV infection can still be accepted if the individual has a disease predictive of a defect in cell-mediated immunity, and there is no known cause of diminished resistance to that disease. The following would cause diminished resistance:

1. High-dosage or long-term systemic corticosteroid therapy or other immunosuppressive/cytotoxic therapy within 3 months before the onset of the indicator disease.

2. Any of the following diseases diagnosed within 3 months of the indicator disease:

a. Hodgkin's disease;

b. Non-Hodgkin's Lymphoma (other than primary brain lymphoma);

c. Lymphocytic leukemia;

d. Multiple myeloma;

e. Other cancer of lymphoreticular or histiocytic tissue; or

f. Angioimmunoblastic lymphadenopathy.

3. A genetic (congential) immunodeficiency syndrome or an acquired immunodeficiency syndrome atypical of HIV infection, such as one involving hypogammaglobulinemia.

When tests are not available, full details of the history, clinical course, and results of serological testing, microbiologic cultures, or tissue biopsy must be documented. The documentation of HIV infection will rely on clinical history, physical examination, exclusion of other causes for the clinical abnormalities, and treating source opinion.

If HIV infection is not documented by the evidence described previously, see item 1 of "Manifestation of HIV Infection in Adults."

Pneumocystis carinii pneumonia (PCP) as described in item 2.b of "Manifestations of HIV Infection in Adults" is the most common opportunistic disease associated with HIV infection. While it is definitively diagnosed by histology or cytology, a diagnosis of PCP may be based on clinical impressions and response to treatment. Medical judgment must be exercised when PCP or other opportunistic diseases are diagnosed without microscopic evidence.

It will often be necessary to obtain a detailed description of daily activities to describe functional limitations or abilities for those cases which require an assessment of residual functional capacity (RFC). This information is essential for evaluation under item 13 in "Manifestation of HIV Infection in Adults" including special documentation for item "d" to evaluate the four general areas of functioning.

Evaluation of HIV Infection in Adults

As with all medically determinable impairments, the assessment of severity must take into account signs, symptoms, and laboratory findings.

In evaluating HIV infection, the impact of all impairment(s) must be considered. Many individuals with HIV infection manifest mental signs and symptoms such as anxiety, depression, apathy, and cognitive impairment. Medical evidence should include documentation of mental impairment when pertinent and the impairment(s) should be evaluated under the appropriate listing(s). These signs and symptoms must also be factored into the assessment of RFC when applicable.

The impact of therapy must also be considered. The therapeutic regimens and consequent adverse response to therapy may vary; therefore, each case must be evaluated on an individual basis. It is essential to obtain a specific description of drugs given, dosage, frequency of administration, and a description of the complications or any other adverse response to therapy. In many instances the effect is temporary and/or dose-related; however, on occasion, the adverse effect may be permanent or long-term.

Medical judgment must be exercised when PCP or other opportunistic diseases are diagnosed without microscopic evidence to establish whether the impairment equals the severity of the listings.

For individuals with HIV infection evaluated under item 13 in the "Manifestations of HIV Infection in Adults" listing-level severity will be assessed in terms of the function limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the claimant's ability to function in a work setting must be considered. Important factors to be considered in evaluating the functioning of individuals with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

Where "marked" is used as standard for measuring the degree of functional limitations, it means more than moderate, but less than extreme. A marked limitation may arise when several activities or functions are impaired or even when only one is impaired, so long as the degree of limitation is such as to seriously interfere with the ability to function independently, appropriately, and effectively.

The four general areas of functioning in which the functioning of HIV-infected individuals is to be assessed are: Activities of daily living; social functioning; difficulties in completing tasks due to deficiencies in concentration, persistence, or pace; and repeated episodes of deterioration or decompensation in work or work-like settings. These areas of functioning provide a framework for the evaluation of the specific functional limitations of the individual. Functional limitations should always be assessed on a case-by-case basis.

For the first general area of functioning, activities of daily living, "marked" means that most of the time the individual is unable to perform daily activities independently. Activities of daily living include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, and paying bills. For example, an HIV-infected person, because of symptoms, such as pain, or the fatigue imposed by the illness or its treatment, or the side effects of medication, may be able to

perform some selfcare activities but not be able to maintain a household, or take public transportation on a sustained, regular basis or without assistance.

For the second general area of functioning, social functioning (i.e., the individual's capacity to interact appropriately and communicate effectively with others), "marked" means that most of the time the individual is unable to sustain interaction and communication. For example, an HIV-infected person may be restricted from engaging in social interaction on a sustained basis. These restrictions could also result from a pattern of exacerbation and remission caused by the illness itself or its treatment.

For the third general area of functioning, "marked" means that most of the time the individual is unable to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. The HIV-infected person may be restricted in this area by the impact of the disease process itself on his or her mental or physical functioning, or both. This could result from extended or intermittent symptoms, such as depression, fatigue, or pain, resulting in a limitation on the ability to concentrate, to persevere at the task, or to perform the task at an acceptable rate of speed. Limitations may also result from the side effects of medication which limit the ability of the person to complete tasks or to sustain activity.

For the fourth general area of functioning, repeated episodes of deterioration or decompensation in work or work-like settings refers to frequent inability to adapt to the work setting or recurrent significant limitations in this ability. This may be caused by manifestations of HIV infection itself, such as its symptoms, or by the frequency and intrusiveness of treatment for the disease. For example, repeated episodes of deterioration could include frequent hospitalizations because of exacerbations of HIV manifestations or medical need to be absent from work imposed on the person because of immunosuppression.

Because of the known high mortality rate in many symptomatic HIV infection cases, for purposes of duration, that aspect of the definition of disability, "expected to result in death," is met if the criteria listed in this Ruling are met. Therefore, an individual with an impairment that meets these criteria would meet the duration requirement under §§ 404.1509 and 416.909 of the regulations.

Those individuals who do not meet the criteria in this Ruling, but who have evidence of severe, symptomatic HIV infection, must be assessed on a case-by-case basis following the sequential evaluation process.

Some individuals infected with HIV are asymptomatic and have no identifiable severe impairment. Other individuals with documented HIV infection may manifest signs and symptoms, such as generalized lymphadenopathy, moderate weight loss, fever, diarrhea, malaise and lethargy, lymphopenia, anemia, thrombocytopenia, or mucosal candidiasis that are of less than the severity described in this Ruling (which is considered to be of listing-level severity). Individuals who have an impairment with a level of severity which is not of listing-level may or may not have the RFC to engage in substantial gainful work activity. Evaluation of the impairment of these individuals should proceed through the final steps of the sequential evaluation process or, as appropriate, the steps in the medical improvement review standard.

Assessment of RFC must take into account the individual's ability to perform work-related activities over time such as a 6- to 8-hour day for 5 days a week. If abilities cannot be sustained over time, this should be noted in the RFC. Since many individuals may be limited significantly by symptoms, such as fatigue, shortness of breath, or side effects of drugs, the impact of symptoms on RFC must be considered.

Special Evaluation Issues in Women

Most women with end-stage HIV infection exhibit the typical opportunistic infections and other conditions, such as pneumocystis carinii pneumonia, candida esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However, HIV infection may manifest itself differently in women than in men. Adjudicators must carefully scrutinize the medical evidence and be alert to the variety of medical conditions specific to women which may or may not affect their ability to function in the work place. Examples include, but are not limited to:

1. Vulvovaginal candidiasis ("yeast infection," monilia). Although this condition usually heals quickly with appropriate treatment, in women with weak immune systems the disorder may become chronic or recurrent, painful and respond poorly to therapy. See item 13.C.6 in "Manifestations of HIV Infection in Adults."

2. Genital herpes. Although the lesions usually occur in limited areas (such as the cervix), as HIV infection progresses the herpes may involve more widespread anatomical areas and may be chronic or recurrent, painful and resistant to therapy. See item 5.b in "Manifestations of HIV Infection in Adults."

3. Pelvic inflammatory disease. This is a condition characterized by infection of the pelvic structures usually caused by infection with a sexually transmitted pathogen such as gonococcus (gonorrhea), chlamydia, or mycoplasma. Disease may be facilitated by an intrauterine device (IUD). In women infected with HIV, there may be resistance to therapy and recurrent episodes of inflammation and pain.

These gynecologic manifestations are also present in the general population but may be more severe in the immunosuppressed individual. It is important when evaluating the claim of a woman with HIV infection, that gynecologic problems be considered in assessing the severity of their impairment and their functional limitations. Gynecologic conditions may or may not severely affect one's ability to function. These conditions should be considered together with all other conditions to determine if the impairment equals the severity of the listings, or if not, to assess functional capacity. (This policy also applies to older female children (adolescents).)

Manifestations of HIV Infection in Adults

An individual will have an impairment that equals the listings if the criteria in one of the following (1 through 13) are met:

1. If there is no documentation of HIV infection as described in "Documentation of HIV Infection in Adults" and the person has no other cause of immunodeficiency, one or more of the following diseases should be present:

a. Candidiasis of the esophagus, trachea, bronchi, or lungs (demonstrated by biopsy, microscopy of a "wet" preparation, or culture); or

b. Cryptococcosis, extrapulmonary (demonstrated by culture, antigen detection in the cerebrospinal fluid (CSF), India-ink preparation of the CSF, or by biopsy); or

c. Cryptosporidiosis with diarrhea persisting over 1 month (documented by intestinal biopsy or fecal microscopy); or

d. Cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes (demonstrated by culture or histology); or

e. Herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; or

bronchitis, pneumonitis, or esophagitis for any duration (demonstrated by culture, histology or cytology); or

f. Lymphoma of the brain (primary) affecting a patient less than 60 years of age; or

g. Mycobacterium avium complex or M. kansasii disease, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes) (demonstrated by culture); or

h. Pneumocystis carinii pneumonia (documented by lung biopsy, microscopy of a "touch" preparation, bronchial washings, or induced sputum); or

i. Progressive multifocal leukoencephalopathy; or

j. Toxoplasmosis of the brain.

Or

2. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following protozoan or helminthic infections:

a. Intestinal cryptosporidiosis (documented by intestinal biopsy or fecal microscopy) that has caused diarrhea for 1 month or more; or

b. Pneumocystis carinii pneumonia (documented by lung biopsy, microscopy of a "touch" preparation, bronchial washings, or induced sputum); or

c. Toxoplasmosis (documented by histology or microscopy of a "touch" preparation) with involvement of an organ other than the liver, spleen, or lymph nodes; or

d. Isosporiasis (documented by intestinal biopsy or fecal microscopy) that has caused diarrhea for a month or more; or

e. Extra-intestinal strongyloidiasis.

Or

3. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following fungal infections:

a. Candidiasis, disseminated (beyond the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes) or involving the esophagus, trachea, bronchi, or lungs (and demonstrated by microscopy of a "wet" preparation, or observation on endoscopy of white plaques on an erythematous base); or

b. Cryptococcosis, disseminated (beyond the lungs), or involving the central nervous system (and demonstrated by culture, antigen detection in the CSF, India-ink preparation of the CSF, or by biopsy); or

c. Disseminated histoplasmosis (beyond the lungs or lymph nodes and demonstrated by culture or biopsy); or

d. Disseminated coccidioidomycosis (beyond the lungs or lymph nodes and demonstrated by culture or histology).

Or

4. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and mycobacterial infection, disseminated (beyond the lungs, lymph nodes, or skin) and demonstrated by culture or by microscopy showing acid fast bacilli of a species not identified by culture.

5. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following viral infections:

a. Cytomegalovirus, causing infection of organs other than the liver, spleen, or lymph nodes and demonstrated by culture or histology; or

b. Herpes simplex virus, causing chronic continuous, (longer than 1 month) mucocutaneous infection or infection of the pulmonary or gastrointestinal tracts or encephalitis or disseminated infection demonstrated by culture, histology, or cytology; or

c. Progressive multifocal leukoencephalopathy.

Or

6. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following bacterial infections:

a. Recurrent non-typhoid salmonella bacteremia; or

b. Nocardiosis (demonstrated by culture).

7. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and HIV encephalopathy, characterized by cognitive and/or motor dysfunction that limit function and progress over weeks and months in the absence of a concurrent illness that could explain the findings.

Or

8. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and HIV wasting syndrome, characterized by involuntary weight loss (more than 10 percent of baseline body weight) and either chronic diarrhea (2 or more loose stools per day for 2 months or more) or chronic weakness and documented fever (greater than 100.4° F for the majority of 2 months or longer) in the absence of a concurrent illness that could explain the findings.

Or

9. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following neoplasms:

a. Lymphoma of the brain; or

b. Other Non-Hodgkin's lymphoma of B-cell or unknown phenotype and histology indicating either:

(1) Burkitt's or other small noncleaved lymphoma; or

(2) Immunoblastic sarcoma.

Or

10. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and one of the following neoplasms:

a. Non-Hodgkin's lymphoma or Hodgkin's disease;

b. Invasive carcinoma of the cervix, FIGO stage II and beyond; or

c. Anal squamous cell carcinoma.

Or

11. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and cardiomyopathy as described under the criteria in Listing 4.02, 4.04, or 4.05.

12. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and nephropathy as described under the criteria in Listing 6.02 or 6.06.

Or

13. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Adults," and the criteria listed below. (The level of severity is met when the requirements for both a and d, both b and d, or both c and d are satisfied.)

a. Impaired cellular immunity as manifested by a CD4 (T4) lymphocyte count less than or equal to 200 cells/mm^3 (or 14 percent or less lymphocytes);

Or

b. One or more of the following persistent and/or resistant to therapy:

(1) Pneumonia; or

(2) Pulmonary tuberculosis; or

(3) Bacterial or fungal sepsis; or

(4) Meningitis; or

(5) Septic arthritis; or

(6) Endocarditis; or

(7) Peripheral neuropathy; or

(8) Kaposi's sarcoma;

Or

c. Two or more of the following persisting over a 2-month period:

(1) Anemia, (hematocrit (HCT) less than or equal to 30 percent); or

(2) Granulocytopenia (absolute neutrophil count less than or equal to 1000/mm^3); or

(3) Thrombocytopenia (less than or equal to 40,000/mm^3); or

(4) Documented fever (greater than or equal to 100.4° F or 38° C); or

(5) Weight loss of greater than or equal to 10 percent of baseline body weight; or

(6) Mucosal (including vulvovaginal) candidiasis other than listed in 1.a and 3.a above; or

(7) Oral hairy leukoplakia; or

(8) Chronic or recurrent Herpes Zoster; or

(9) Persistent dermatological conditions such as eczema, or psoriasis; or

(10) Persistent, unresponsive diarrhea; or

(11) Persistent or recurrent radiographically documented sinusitis;

Or

d. At least two of the following:

(1) Market restriction of activities of daily living; or

(2) Marked difficulties in maintaining social functioning; or

(3) Marked difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace; or

(4) Repeated episodes of decompensation, averaging 3 times a year or once every 4 months, lasting 2 or more weeks each, which cause the individual to deteriorate (which may include loss adaptive functioning).

Documentation of HIV Infection in Children

The medical file should be documented by the findings of a thorough history and physical examination. The onset and nature of signs and symptoms should be specifically and clearly described. Attempts should be made to quantify the extent and severity of all signs and symptoms. The variability or intensity of signs, symptoms, and laboratory findings over time should also be indicated.

The medical evidence should include documentation of HIV infection and specific laboratory evidence of an opportunistic disease, cancer, or other condition. In obtaining information regarding HIV antibody or viral testing, requirements of State and local laws governing the release of information must be met.

Laboratory evidence of HIV infection in children includes:

1. For children from birth to attainment of 1 year of age, HIV infection should be documented by one of the following:

a. a serum specimen that contain HIV antigen; or

b. A blood or CSF culture positive for HIV, confirmd by a specific test for the antigen; or

c. Other tests believed to be highly specific for detection of HIV (e.g., polymerase chain reaction (PCR)); or

d. A CD4 (T4) count of 1500 per mm ^{3} or less, or a CD4 count less than or equal to 20 percent of total lymphocytes.

2. For children 1 year of age to 15 months of age, HIV infection should be documented by one of the following:

a. A serum specimen that contains HIV antigen; or

b. A blood or CSF culture positive for HIV, confirmed by a specific test for the antigen; or

c. Other tests believed to be highly specific for detection of HIV (e.g., PRC); or

d. A CD4 (T4) count of 750 per mm ^{3} or less, or a CD4 count less than equal to 20 percent of total lymphocytes.

3. For children 15 months of age or older, HIV infection should be documented by one of the following:

a. A serum specimen that contains HIV antibodies, detected by a screening test (e.g., ELISA) and confirmed by a more definitive test (e.g., Western blot, immunofluorescence assay), or

b. A serum specimen that contains HIV antigen, or

c. A lymphocyte culture, positive for HIV, confirmed by a specific test for the antigen, (not just detection of reverse transcriptase).

d. Other tests believed to be highly specific for detection of HIV (e.g., PCR).

When the above tests are not part of the medical evidence in the file, a diagnosis of HIV infection can be accepted if the individual has a disease predictive of a defect in cell-mediated immunity, and there is no known cause of diminished resistance to that disease. (See "Documentation of HIV Infection in Adults" for causes of diminished resistance.)

When tests are not available, full details of the history, clinical course, and results of serological testing, microbiologic cultures, or tissue biopsy must be documented. The documentation of HIV infection will rely on clinical history, physical examination, exclusion of other causes for the clinical abnormalities, and treating source opinion.

If HIV infection is not documented by the evidence described previously, see item 1 of "Manifestation of HIV infection in Children."

Pneumocystis carinii pneumonia (PCP) as described in item 2.b of "Manifestations of HIV Infection in Children" is one of the most common opportunistic disease associated with HIV infection. While it is definitively diagnosed by histology or cytology, a diagnosis of PCP may be based on clinical impressions and response to treatment. Medical judgment must be exercised when PCP or other opportunistic diseases are diagnosed without microscopic evidence.

All relevant evidence regarding the child's impairment(s) and the functional effects of the impairment(s) on the child's ability to grow, develop, or mature in an age-appropriate manner should be obtained. This information is essential for evaluation under items 12 and 13 in "Manifestations of HIV Infection in Children."

Evaluation of HIV Infection in Children

As with all medically determinable impairments, the assessment of severity must take into account signs, symptoms, and laboratory findings. Development and assessment of age-appropriate activities (the effect of the impairment(s) on the child's ability to grow, develop, or mature in an age-appropriate manner) may also be helpful in evaluating the severity of the impairment.

In evaluating HIV infection, the impact of all impairments must be considered. Children with HIV infection may manifest mental signs and symptoms such as anxiety, depression, apathy, and cognitive impairment. Medical evidence should include documentation of mental impairment when pertinent and the impairment(s) should be evaluated under the appropriate listing(s). These signs and symptoms must also be factored into the individualized functional assessment, when applicable.

The impact of therapy must also be considered. The therapeutic regimens and consequent adverse response to therapy may vary: therefore, each case must be evaluated on an individual basis.

It is essential to obtain a specific description of the drugs given, dosage, frequency of administration, and a description of the complications or any other response to therapy. In many instances the effect is temporary and/or dose-related; however, on occasion, the adverse effect may be permanent or long-term.

For children with HIV infection evaluated under items 12 or 13 in "Manifestations of HIV Infection in

Children," listing-level severity will be assessed in terms of the functional limitations imposed by the manifestations of the impairment. The full impact of signs, symptoms, and laboratory findings on the child's ability to grow, develop, or engage in age-appropriate activities must be considered. Important factors to be considered in evaluating the functioning of children with HIV infection include, but are not limited to: Symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

To meet the standards in item 12, for children age 12 or younger, the HIV-infected child must demonstrate the appropriate degree and number of limitations for his or her age in Listing 112.02, paragraph B1 (for children age 1 to attainment of age 3) or paragraph B2 (for children age 3 to attainment of age 13), or in any paragraph of Listing 112.12 (for children from birth to the attainment of age 1). To meet the standards in item 13, a child age 13 to the attainment of age 18 must demonstrate marked restriction in at least two of the four general areas of functioning in Listing 112.02, paragraph B2.

We will exercise medical judgment when PCP or other opportunistic diseases are diagnosed without microscopic evidence to establish whether the impairment equals the severity of the listings.

Because of the known high mortality rate in many symptomatic HIV infection cases, for purposes of duration, that aspect of the definition of disability, "expected to result in death," is met if the criteria listed in this Ruling are met. Therefore, a child with an impairment that meets these criteria would meet the duration requirement under § 416.909 of the regulations.

Children may or may not have impairments that are equivalent to listing-level severity and, if not, may or may not have impairments of comparable severity to those that would disable an adult based on an individualized functional assessment (IFA). If the child's impairment or impairments do not meet or equal a listing (medically or functionally), an IFA is crucial to the evaluation of whether the child is disabled.

Special Evaluation Issues For Children

Younger children with HIV infection differ from adults in the mode of infection, clinical manifestation, and course of disease. Younger children may acquire infection from the mother or from transfusion of contaminated blood or blood products (such as coagulation factors) or, rarely, as a result of sexual abuse. In addition, survival times are shorter for children infected in the first year of life compared to older children and adults.

The mean age of diagnosis of children infected before or shortly after birth is 17 months but a diagnosis may be made much earlier. The majority develop failure to thrive, pneumonia, enlarged livers and spleens. Infants will commonly have candida infection, failure to thrive, pheumocystis carinii pneumonia (PCP); 2-year-olds may present with parotitis, enlarged lymph nodes, recurrent infections, neurologic problems, and development abnormalities.

Although in children, as well as adults, T-helper lymphocyte (CD4) counts decrease as disease progresses, infants and young children have much higher CD4 counts than adults. Children with significant immunosuppression can have CD4 counts which would fall within the normal range for adults.

Mothers with HIV infection usually transfer HIV antibodies to their newborns and therefore, these infants will have HIV antibodies in their serum. Therefore, this finding does not necessarily in itself establish the presence of HIV infection in the infant. Because the presence of HIV infection in young children can be difficult to confirm, evidence of significantly depressed CD4 counts may also be used to establish that a disease or condition is in fact related to HIV infection.

Older children (adolescents) may become infected from contaminated blood or blood products or due to behaviors such as intravenous drug use and unprotected sexual relations. The course and spectrum of disease in children age 13 and older generally is similar to that of adults. Some children, particularly older children, may exhibit HIV encephalopathy or HIV wasting syndrome as described in "Manifestation of HIV Infection in Adults" and should be evaluated under that section when applicable.

Manifestations of HIV Infection in Children

A child will have an impairment that equals the listings if the criteria listed in one of the following (1 through 13) are met:

1. If there is no documentation of HIV infection as described in "Documentation of HIV Infection in Children" and the child has no other cause of immunodeficiency, one or more of the following diseases should be present:

a. Candidiasis of the esophagus, trachea, bronchi, or lungs (demonstrated by biopsy, microscopy of a "wet" preparation, or culture); or

b. Cryptococcosis, extrapulmonary (demonstrated by culture, antigen detection in the CSF, India-ink preparation of the CSF, or by biopsy); or

c. Cryptosporidiosis with diarrhea persisting over 1 month (documented by intestinal biopsy or fecal microscopy); or

d. Cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes in a child over 1 month of age (demonstrated by culture or histology); or

e. Herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; or bronchitis, pneumonitis, or esophagitis for any duration affecting a child over 1 month of age (demonstrated by culture, histology or cytology); or

f. Lymphoma of the brain (primary); or

g. Lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PLH complex) affecting a child less than 13 years of age (demonstated by biopsy); or

h. Mycobacterium avium complex or M. kansasii disease, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes) (demonstrated by culture); or

i. Pneumocystis carinii pneumonia (documented by lung biopsy, microscopy of a "touch" preparation, bronchial washings, or induced sputum); or

j. Progressive multifocal leukoencephalopathy; or

k. Toxoplasmosis of the brain affecting a child over 1 month of age.

Or

2. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and one of the following protozoan or helminthic infections:

a. Intestinal cryptosporidiosis (documented by intestinal biopsy or fecal microscopy) that has caused diarrhea for a month or more; or

b. Pneumocystis carinii pneumonia (documented by lung biopsy, microscopy or a "touch" preparation, bronchial washings, or induced sputum); or

c. Toxoplasmosis (documented by histology or microscopy of a "touch" preparation) with involvement of an organ other than the liver, spleen, or lymph nodes; or

d. Isosporiasis (documented by intestinal biopsy or fecal microscopy)

that has caused diarrhea for a month or more; or

e. Extra-intestinal strongyloidiasis.

Or

3. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and one of the following fungal infections:

a. Candidiasis, disseminated (beyond the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membrances) or involving the esophagus, trachea, bronchi, or lungs (and demonstrated by microscopy of a "wet" preparation, or observation on endoscopy of white plaques on an erythematous base); or

b. Cryptococcosis, disseminated (beyond the lungs), or involving the central nervous system (and demonstrated by culture, antigen detection in the CSF, India-ink preparation of the CSF, or by biopsy); or

c. Disseminated histoplasmosis (beyond the lungs or lymph nodes and demonstrated by culture or biopsy); or

d. Disseminated coccidioidomycosis (beyond the lungs or lymph nodes and demonstrated by culture or by histology).

Or

4. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and mycobacterial infection, disseminated (beyond the lungs, lymph nodes, or skin and demonstrated by culture or by microscopy showing acid fast bacilli of a species not identified by culture);

Or

5. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and one of the following viral infections:

a. Cytomegalovirus, causing infection of organs other than the liver, spleen, or lymph nodes and demonstrated by culture or histology; or

b. Herpes simplex virus, causing chronic, continuous (longer than 1 month), mucocutaneous infection or infection of the pulmonary or gastrointestinal tracts or encephalitis or disseminated infection demonstrated by culture, histology, or cytology; or

c. Progressive multifocal leukoencephalopathy.

Or

6. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and bacterial infections of one of the following types:

a. Multiple or recurrent bacterial infections (i.e., two or more within a 2-year period of time) of the following types affecting a child less than 13 years of age: septicemia, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses) caused by pyogenic bacteria; or

b. Nocardiosis (demonstrated by culture); or

c. Recurrent non-typhoid salmonella bacteremia.

Or

7. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PLH complex) affecting a child less than 13 years of age (documented histologically or by a persistent interstitial pattern on chest x-ray for 2 months or more).

Or

8. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and one of the following neoplasms:

a. Lymphoma of the brain; or

b. Other non-Hodgkin's lymphoma of B-cell or unknown phenotype and histology indicating either:

(1) Burkitt's or other small noncleaved lymphoma; or

(2) Immunoblastic sarcoma.

Or

9. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and non-Hodgkin's lymphoma or Hodgkin's disease.

Or

10. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and progressive neurological disease resulting in one or more of the following:

a. Loss of previously acquired or marked delay in achieving developmental milestones or intellectual ability; or

b. Impaired brain growth (acquired microcephaly and/or brain atrophy on scan); or

c. Progressive symmetric motor deficits as manifested by two or more of paresis, abnormal tone, pathologic reflexes, ataxia, or gait disturbance. Some children, particularly older children, may exhibit HIV encephalopathy as described in item 7 of "Manifestations of HIV Infection in Adults." If HIV encephalopathy is involved, evaluate under that criterion.

Or

1. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," and failure to thrive or a falling off from the age-appropriate range of the projected growth curve. Evaluate under Listing 100.02. Older children may exhibit HIV wasting syndrome as described in item 8 of "Manifestations of HIV Infection in Adults." If HIV wasting syndrome is involved, evaluate under that criterion.

Or

12. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," in children age 12 or younger with the criteria listed below. (The level of severity is met when the requirements for both a and c are satisfied, or both b and c are satisfied.)

a. One or more of the following persistent and/or resistant to therapy:

(1) Pneumonia; or

(2) Pulmonary tuberculosis; or

(3) Bacterial or fungal sepsis; or

(4) Meningitis; or

(5) Septic arthritis; or

(6) Endocarditis; or

(7) Peripheral neuropathy; or

(8) Kaposi's sarcoma;

Or

b. Two or more of the following persisting for at least 2 months:

(1) Fever (greater than or equal to 100.4° F or 38° C); or

(2) Hepatomegaly; or

(3) Splenomegaly; or

(4) Generalized lymphadenopathy; or

(5) Parotitis; or

(6) Diarrhea (defined as 3 or more loose stools daily or at least 2 recurrent episodes associated with dehydration); or

(7) Persistent dermatological conditions such as eczema, psoriasis; or

(8) Weight loss greater than 10 percent; or

(9) Persistent or recurrent radiographically documented sinusitis;

And

c. For children from:

(1) Birth to attainment of age 1, at least one of the criteria in paragraphs A–E of Listing 112.12; or

(2) Age 1 to attainment of age 3, at least one of the appropriate age-group

criteria in paragraph B1 of Listing 112.02; or

(3) Age 3 to attainment of age 13, at least two of the appropriate age-group criteria in paragraph B2 of Listing 112.02.

Or

13. Documentation of HIV infection as described in the section, "Documentation of HIV Infection in Children," in children age 13 or older with the criteria listed below. (The level of severity is met when the requirements for both a and d, both b and d, or both c and d are satisfied.)

a. Impaired cellular immunity as manifested by a CD4 (T4) lymphocyte count less than or equal to 200 cells/mm^3 (or 14 percent or less lymphocytes);

Or

b. One or more of the following persistent and/or resistant to therapy:

(1) Pneumonia; or
(2) Pulmonary tuberculosis; or
(3) Bacterial or fungal sepsis; or
(4) Meningitis; or
(5) Septic arthritis; or
(6) Endocarditis; or
(7) Peripheral neuropathy; or
(8) Kaposi's sarcoma;

Or

c. Two or more of the following persisting over a 2 month period:

(1) Anemia, (hematocrit (Hct) less than or equal to 30 percent); or
(2) Granulocytopenia (absolute neutrophil count less than or equal to 1000/mm^3; or
(3) Thrombocytopenia (less than or equal to 40,000/mm^3); or
(4) Documented fever (greater than or equal to 100.4°F or 38° C); or
(5) Weight loss of greater than or equal to 10 percent of baseline body weight; or
(6) Mucosal (including vulvovaginal) candidiasis other than listed in 1.a or 3.a above; or
(7) Oral hairy leukoplakia; or
(8) Chronic or recurrent Herpes Zoster; or
(9) Persistent dermatological conditions such as eczema, or psoriasis; or
(10) Persistent, unresponsive diarrhea; or
(11) Persistent or recurrent radiographically documented sinusitis;

And

d. At least two of the appropriate age-group criteria in paragraph B2 of Listing 112.02.

Onset of Disability For Adults

The onset of disability should be based on allegations, work history, and the medical and other evidence concerning impairment severity. Onset in cases of symptomatic HIV infection cases will be no later than the date medical findings show that the impairment is disabling unless the individual is engaging in substantial gainful activity (SGA).

An earlier onset date of disability may be established if supported by the documented findings in the case. In some cases, it may be reasonable to infer that the onset occurred some time prior to the first recorded medical examination, provided the claimant was not engaging in SGA. However, an automatic date (e.g., 6 months prior to medical evidence) should not be inferred; the inference must be made based on all of the facts in each individual case.

EFFECTIVE DATE: December 17, 1991.

Cross-Reference: Program Operations Manual System, Part 04, sections DI 24525.001–.045

[FR Doc. 91–30032 Filed 12–16–91; 8:45 am]
BILLING CODE 4190–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–220–4320–12–241A]

Information Collection submitted to the Office of Management and Budget for Review Under Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau's Clearance Officer and to the Office of Management and Budget, Paperwork Reduction Project (1004–0005), Washington, DC 20503, telephone (202) 395–7340.

Title: Grazing Application-Grazing Schedule.

OMB Approval Number: 1004–0005.

Abstract: This form is used by permittees to apply for annual authorization to graze livestock on the Public lands.

Bureau Form Number: 4130–1.

Frequency: On occasion/annually.

Description of Respondents: Applicants requesting authorizations to graze livestock on the public lands.

Estimated completion time: 20 minutes.

Annual Responses: 6,000.

Annual Burden Hours: 2,000.

BLM Clearance Officer (Alternate): Gerri Jenkins, (202) 653–8853.

Dated: July 26, 1991.

Michael J. Penfold,

Assistant Director, Land and Renewable Resources.

[FR Doc. 91–29992 Filed 12–16–91; 8:45 am]
BILLING CODE 4310–84–M

[WO–220–4320–12–241A]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau's Clearance Officer and to the Office of Management and Budget, Paperwork Reduction Project (1004–0051), Washington, DC 20503, telephone (202) 395–7340.

Title: Actual Grazing Use Report.

OMB Approval Number: 1004–0051.

Abstract: This form is used by permittees to provide information on the actual amount of livestock grazing use made on the public lands within a specified time to the Bureau of Land Management for billing purposes and program monitoring.

Bureau Form Number: 4130–5.

Frequency: Annually.

Description of Respondents: Permittees required to report actual Livestock uses on the Public Lands.

Estimated Completion Time: 24 minutes.

Annual Responses: 15,000.

Annual Burden Hours: 6,000.

Bureau Clearance Officer (Alternate): Gerri Jenkins (202) 653–8853.

Dated: July 26, 1991.

Michael J. Penfold,

Assistant Director, Land and Renewable Resources.

[FR Doc. 91–29993 Filed 12–16–91; 8:45 am]
BILLING CODE 4310–84–M

[CA-020-4760-02;]

Closure of Land; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency closure of use on public lands; Modoc County, California.

SUMMARY: Notice is hereby given that use of selected public lands southeast of the City of Alturas, Modoc County, California, is closed to the public until further notice. Access to these lands, commonly known as the site of the Yankee Jim Ranch homestead, is limited to authorized personnel from the Bureau of Land Management on official business, or other persons specifically authorized by the Susanville District Manager or the Alturas Area Manager of the Bureau of Land Management. This closure is necessary to protect persons and property from coming into contact with a hazardous materials site.

DATES: This closure goes into effect on December 10, 1991 and shall remain in effect until revoked or modified by the authorized officer.

FOR FURTHER INFORMATION CONTACT: Rich Burns, Area Manager, Alturas Resource Area, 608 W. 12th Street, Alturas, California 96101. Telephone: (916) 233-4666.

SUPPLEMENTARY INFORMATION: The authority for this closure is title 43, Code of Federal Regulations, part 8364.1 (43 CFR 8364.1). Any person who fails to comply with this order is subject to arrest and fine of up to $1,000 and/or imprisonment not to exceed 12 months. This closure applies to all members of the public except persons authorized by the Bureau of Land Management. This closure affects the following described public Land Management. This closure affects the following described public land:

Mount Diablo Meridian, California

T. 41 N., R. 14 E.
sec. 17, NE¼.

The site commonly known as the Yankee Jim Ranch homestead.

Dated: December 9, 1991.

Robert J. Sherve;

Associate District Manager.

[FR Doc. 91-30100 Filed 12-16-91: 8:45 am]

BILLING CODE 4310-40-M

[CO-942-92-4730-12]

Colorado: Filing of Plats of Survey

December 9, 1991

The plat of survey of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10 a.m., December 9, 1991.

The plat representing the dependent resurvey of portions of the Second Standard Parallel South (S. bdy.), T. 10 S., Rs. 88 and 89 W., the Eleventh Guide Meridian West (W. bdy.), and the subdivisional lines; the subdivision of certain sections; and a metes-and-bounds survey of certain lots in section 7, T. 11 S., R. 88 W., Sixth Principal Meridian, Colorado, Group No. 899, was accepted December 3, 1991.

This survey was executed to meet certain administrative needs of the U.S. Forest Service.

All inquires about this land should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado, 80215.

Jack A. Eaves,

Chief, Cadastral Surveyor for Colorado.

[FR Doc. 91-30037 Filed 12-16-91; 8:45 am]

BILLING CODE 4310-JB-M

National Park Service

General Management Plan; Organ Pipe Cactus National Monument, AZ; Notice of Intent to Prepare an Environmental Impact Statement

SUMMARY: The National Park Service will prepare an environmental impact statement (EIS) in conjunction with the General Management Plan (GMP) for Organ Pipe Cactus National Monument, Arizona. This notice is in accordance with 40 CFR 1501.7 and 40 CFR 1508.22, of the regulations of the President's Council on Environmental Quality for the National Environmental Policy Act of 1969, Public Law 91-150. The GMP/EIS will describe and analyze a proposal and alternatives for the future management of the monument.

BACKGROUND: Prior to making the determination that an EIS would be required, the National Park Service initiated the scoping process for the GMP by publishing notice in the **Federal Register**, page 21487, Vol. 54, No. 95 of May 18, 1989. A 60 day public comment period on plan considerations was allowed at that time. Subsequently, numerous meetings have been held with adjacent land owners, other monument neighbors and interest groups regarding the future management directions for the monument.

Any additional persons or organizations wishing to comment or express concerns on future management directions for Organ Pipe Cactus National Monument, should address such comments or any questions to: Superintendent, Organ Pipe Cactus National Monument, Route 1, Box 100, Ajo, AZ 85321. These comments should be received within 30 days of the publication of this notice.

The responsible official is Stanley T. Albright, Regional Director, Western Region, National Park Service. The draft GMP/EIS is expected to be available for public review in fall 1992, and the final GMP/EIS and Record of Decision completed approximately one year later.

Dated: December 5, 1991.

Lewis Albert,

Acting Regional Director, Western Region.

[FR Doc. 91-30097 Filed 12-16-91; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

Agency Information Collection Under OMB Review

The following proposals for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35) are being submitted to the Office of Management and Budget for review and approval. Copies of the forms and supporting documents may be obtained from the Agency Clearance Officer, Kathleen King, (202) 927-5493. Comments regarding this information collection should be addressed to Kathleen King, Interstate Commerce Commission, room 1312, Washington, DC 20423 and to Ed Clark, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503. When submitting comments, refer to the OMB number of the title of the Form.

Type of Clearance: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection

Bureau/Office: Office of Economics.

Title of Form: Annual Report to the Interstate Commerce Commission.

OMB Form Number: 3120-0029.

Agency Form Number: ACAA-R-1

Frequency: Annual.

Respondents: Class I Railroads.

No. of Respondents: 21.

Total Burden Hours: 16,800.

Type of Clearance: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

Bureau/Office: Office of Economics.

Title of Form: Annual Report to the Interstate Commerce Commission.

OMB Form Number: 3120-0032

Agency Form Number: Form M.

Frequency: Annual.

Respondents: Class I and II Motor Carriers of Property.
No. of Respondents: 2017.
Total Burden Hours: 50,425.
Type of Clearance: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.
Bureau/Office: Office of Economics.
Title of Form:
Motor Carrier Quarterly Report Form.
OMB Form Number: 3120–0002.
Agency Form Number: Form QFR.
Frequency: Quarterly.
Respondents: Class I and II Motor Carriers of Property and Household Goods.
No. of Respondents: 896.
Total Burden Hours: 7168.
Type of Clearance: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.
Bureau/Office: Office of Economics.
Title of Form: Uniform System of Accounts Motor Carrier of Property.
OMB Form Number: 3120–0106.
Agency Form Number: N/A.
Frequency: Annual.
Respondents: Motor Carriers of Property.
No. of Respondents: 2017.
Total Burden Hours: 284,397.

Sidney L. Strickland, Jr.,
Secretary.

[FR Doc. 91–30054 Filed 12–16–91; 8:45 am]
BILLING CODE 7035–01–FR

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980

In accordance with Departmental policy, 28 CFR 50.7, 42 U.S.C. 6973(d) and 42 U.S.C. 9622(i), notice is hereby given that on December 4, 1991, a proposed consent decree in *United States of America* v. *Anson, Inc., et al.*, Civil Action No. 91–0392–P–C, has been lodged with the United States District Court for the District of Maine. The United States' complaint, filed at the same time as the consent decree, sought recovery of response costs and injunctive relief under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9606 and 9607, against the Adams Co. and 59 other entities responsible for hazardous substances found at the Union Chemical Company Site in South Hope, Maine, a National Priorities List facility.

The consent decree provides that the defendants will perform work to remedy contamination at the Site, in accordance with the Record of Decision (ROD) issued by the U.S. Environmental Protection Agency (EPA), and reimburse EPA for one hundred percent of the estimated present value of all response costs to be incurred by the United States in connection with oversight of the implementation of the ROD. The remedial work will include excavation and treatment of contaminated soils, pumping and treating the contaminated groundwater, monitoring of the groundwater, monitoring of off-site soils and decontamination, demolition, and off-site disposal of facilities located on the Site. The defendants also agree to reimburse EPA for certain past governmental response cost.

The Department of Justice will receive comments relating to the proposed consent decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environmental and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Anson, Inc., et al.*, D.J. Ref. 90–11–2–643A.

The proposed consent decree may be examined at the office of the United States Attorney, EastTower-Sixth Floor, 100 Middle Street Plaza, Portland, Maine, 04101, and at the Region I office of the Environmental Protection Agency, One Congress St., Boston, Massachusetts, 02203. The proposed consent decree may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Washington, DC 20004 (202–347–7829). A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW, Box 1097, Washington, DC 20004. In requesting a copy, please enclose a check in the amount of $20.25 (25 cents per page reproduction cost, exclusive of the costs of copying the appendix and signature pages) payable to the "Consent Decree Library."

Roger Clegg,
Acting Assistant Attorney General, Environmental & Natural Resources Division.

[FR Doc. 91–30103 Filed 12–16–91; 8:45 am]
BILLING CODE 4410–01–M

Lodging of Stipulation and Agreement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended ("CERCLA")

In accordance with section 122(i) of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), 42 U.S.C. 9622(i), and Departmental policy at 28 CFR 50.7, notice is hereby given that a proposed Stipulation and Agreement To Settle and Compromise Claims of the United States in *In re: Bellamah Community Development Co.*, (N. Mex. Bankruptcy Ct.), No. 7–89–01559 MA, was lodged on December 3, 1991, with the United States Bankruptcy Court for the District of New Mexico.

On October 5, 1989, a Proof of Claim was filed by the United States of America against Bellamah Community Development Co., seeking payment of a general unsecured claim of $2,321,910.00 for response costs incurred by EPA in responding to the release or threat of release of hazardous substances from the Compass Landfill Site located near Tulsa, Oklahoma. The United States also claimed as administrative expenses its response costs to be incurred after the filing of its Proof of Claim.

The proposed Stipulation and Agreement settles the United States' claims under section 106 and 107 of CERCLA for $150,000. Bellamah Community Development Co., also provides an irrevocable right of access to the Site to the extent it owns or controls the property.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, written comments relating to the Stipulation and Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *In re: Bellamah Community Development Co.*, DOJ Ref. No. 90–11–3–552.

The proposed Stipulation and Agreement may be examined at the Region 6 office of the Environmental Protection Agency ("EPA"), Twelfth Floor, 1445 Ross Avenue, Dallas, Texas, 75202; and at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue Building, NW., Box 1097, Washington, DC 20004, (202) 347–2072. A copy of the proposed Stipulation and Agreement may be obtained in person or by mail from the Document Center. In requesting a copy of the Stipulation and Agreement, please enclose a check for copying costs in the amount of $3.000 (25 cents per page

reproduction costs), payable to Consent Decree Library.

John C. Cruden,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 91-30104 Filed 12-16-91; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Under Comprehensive Environmental Response, Compensation and Liability Act; Operating Industries, Inc. Site

In accordance with section 122(d)(2)(B) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), and in accordance with the policy of the Department of Justice, 28 CFR 50.7, notice is hereby given that on December 3, 1991, a proposed Third Partial Consent Decree in *United States* v. *Chevron Chemical Company, et al.*, was lodged with the United States District Court for the Central District of California. That action was brought pursuant to sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, for performance of certain remedial action at the Operating Industries, Inc. ("OII") landfill in Monterey Park, California, and for reimbursement of response costs incurred by the United States Environmental Protection Agency ("EPA") in responding to releases and threatened releases of hazardous substances at the OII site.

The Third Partial Consent Decree settles claims against 171 companies and public entities that have entered into the settlement. Pursuant to the consent decree, the defendants will perform substantial portions of the third operable unit at the OII site, for design, construction and operation of a landfill gas migration control system, and design and construction of a landfill cover system, and will reimburse federal and state past costs incurred from June 1, 1988 through December 31, 1990 of approximately $18 million, and pay federal and state oversight costs for performance of the response actions. The total value of the settlement is approximately $130 million. Under the settlement, numerous settlers will be responsible for actual performance of the work, while other settlers are making a cash payment only to resolve their liability and will not be involved in the performance of the work.

As provided in section 122(d)(2)(B) of CERCLA and 28 CFR 50.7, the Department of Justice will receive comments from persons who are not named as parties to this action relating to the proposed Third Partial Consent Decree for a period of thirty days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530. All comments should refer to *United States* v. *Chevron Chemical Company, et al.*, D.J. Ref. 90-11-2-156.

The proposed Third Partial Consent Decree may be examined at the office of the United States Attorney, 312 N. Los Angeles Street, Los Angeles, California 90012, and at the Region IX office of the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, California 94105. A copy of the proposed Third Partial Consent Decree may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Washington, DC 20004, (202) 347-2072. A copy of the proposed Third Partial Consent Decree may be obtained in person or by mail from the Document Center. In requesting a copy, please enclose a check either in the amount of $28.75 for a copy of the consent decree without the exhibits or attachments, or a check in the amount of $108.75 for a copy of the consent decree plus all exhibits and attachments, (25 cents per page reproduction costs) payable to "Consent Decree Library."

Barry M. Hartman,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 91- 30105 Filed 12-16-91; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to the Resource Conservation and Recovery Act

Notice is hereby given that on November 26, 1991, a proposed Consent Decree in *United States* v. *City of Cleveland*, Civil Action No. 1:91 CV 2398, was lodged with the United States District Court for the Northern District of Ohio. The proposed consent decree concerns the Matousek Landfill in Garfield Heights, Ohio. The proposed consent decree requires the City of Cleveland and codefendants Cities of Garfield Heights, North Olmsted, Maple Heights, Brookpark, Parma Heights, Berea, Warrensville Heights, Bedford, University Heights, Seven Hills, Middleburg Heights, Independence, Newburgh Heights, Valley View, and Cuyahoga Heights to pay $412,000 to the United States in settlement costs incurred by the United States relating to the remediation of hazardous conditions posed by leakage of methane gas from the Matousek Landfill.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *City of Cleveland*, D.J. Ref. 90-7-1-483.

The proposed consent decree may be examined at the office of the United States Attorney, suite 500, 1404 East Ninth Street, Cleveland, Ohio 44114, and at the Region V Office of the Environmental Protection Agency, 111 West Jackson Street, Chicago, Illinois 60604.

The proposed consent decree may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Ave., NW., Box 1097, Washington, DC 20004, 202-347-7829. A copy of the proposed consent decree may be obtained in person or by mail from the Document Center. In requesting a copy, please enclose a check in the amount of $7.00 ($.25 per page reproduction costs) payable to the Consent Decree Library.

Barry M. Hartman,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 91-30106 Filed 12-16-91; 8:45 am]

BILLING CODE 4410-01-M

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984—Bell Communications Research, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Bell Communications Research, Inc. ("Bellcore") on November 6, 1991, filed a written notification on behalf of Bellcore and TranSwitch Corporation ("TranSwitch") simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identifies of the parties to the venture and (2) the nature and objective of the venture. The notification was filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture, and its general areas of planned activities, are given below.

Bellcore is a Delaware corporation with its principal place of business in Livingston, New Jersey.

TranSwitch is a Delaware corporation with its principal place of business in Shelton, Connecticut.

Bellcore and TranSwitch entered into an agreement effective as of October 17, 1991 to engage in cooperative research for investigation of internetworking of SONET-based exchange networks with other standard networks, including fabrication of experimental prototypes for the demonstration of SONET capabilities.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 91-30039 Filed 12-16-91; 8:45 am]

BILLING CODE 4410-01-M

Notice Pursuant to the National Cooperative Research Act of 1984—Unix International, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), UNIX International, Inc. ("UNIX") on November 5, 1991, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The additional written notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On January 30, 1989, UNIX filed its original notification pursuant to section 6(a) of the Act. The Department of Justice (the "Department") published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 1, 1989 (54 FR 8608). On May 4, 1989, August 1, 1989, October 31, 1989, January 31, 1990, May 1, 1990, July 30, 1990, November 13, 1990, February 6, 1991, May 17, 1991, and August 12, 1991, UNIX filed additional written notifications. The Department published notices in the **Federal Register** in response to the additional notifications on June 22, 1989 (54 FR 26266), August 17, 1989 (54 FR 33985), November 29, 1989 (54 FR 49124), March 14, 1990 (55 FR 9517), May 21, 1990 (55 FR 20862), September 17, 1990 (55 FR 38173), December 28, 1990 (55 FR 53368), March 15, 1991 (56 FR 11273), June 20, 1991 (56 FR 28417), and September 12, 1991 (56 FR 46445), respectively.

As of November 1, 1991, the following have become members of UNIX International, Inc.:

AIR Company Limited of Tokyo, Japan
ATB Associates of Wellesley, Massachusetts
Bellcore of Piscataway, NJ
COSA—an open systems association of Taiwan, ROC
Eastman Kodak (Japan), Ltd. of Yokohama, Japan
Faculty of Engineering, Hokkaido University of Sapporo, Japan
Institute of Systems Science of Singapore, Republic of Singapore
MEITEC Intelligent Technology Corp. of Tokyo, Japan
NETLABS, Inc. of Los Altos, CA
Roads and Traffic Authority, NSW of Sydney, NSW, Australia
SOFTWAY of Chippendale, NSW, Australia
The Standish Group International of Hyannis, Massachusetts

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 91-30038 Filed 12-16-91; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

B.T.H., Inc., et al.; Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 27, 1991.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 27, 1991.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 2nd day of December 1991.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition No	Articles produced
B.T.H., Inc ILGWU	New York, NY	12/02/91	11/21/91	26,617	Dresses.
Bijur Lubricating Corp (UE)	Bennington, VT	12/02/91	11/22/91	26,618	Lubricating Pumps.
BMY—Wheeled Vehicle Division (Wkrs)	Marysville, OH	12/02/91	11/23/91	26,619	Military Trucks.
CAC Microcircuits, Inc (Wkrs)	Mt. Carmel, IL	12/02/91	11/21/91	26,620	Electronic Circuits.
Chevron Chemical Co (OCAW)	Kennewick, WA	12/02/91	11/15/91	26,621	Dry Fertilizer.
Cinn Milacron Heald Corp (wkrs)	Worecester, MA	12/02/91	11/01/91	26,622	Grinders and Boring Centers.
Country Miss, Inc. ILGWU	Cookeville, TN	12/02/91	11/21/91	26,623	Womens slacks, shorts, skirts.
GEO Western Drilling Fluids (Co.)	Bakersfield, CA	12/02/91	11/03/91	26,624	Drilling Fluids.
Intrex Corp (Wkrs)	Harrison, NJ	12/02/91	11/05/91	26,625	Wood Furniture & Fixtures.
Jay-Zee Merchandising, Inc. (Co)	New York, NY	12/02/91	11/22/91	26,626	Boys and Young Men's Slacks, Pants.
Jay-Zee, Inc. (Co)	Maryland Heights, MO	12/02/91	11/22/91	26,627	Boys and Young Men's Slacks Pants.
Nikki Lee Fashions, Inc ILGWU	Duryea, PA	12/02/91	11/21/91	26,628	Women's Dresses.

APPENDIX—Continued

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition No	Articles produced
PanCanadian Petroleum Co (Co.)	Houston, TX	12/02/91	11/19/91	26,629	Oil, Natural Gas and Liquids.
Parkway Sterling Regal, Inc (ALA)	Carlstadt, NJ	12/02/91	11/21/91	26,630	Lithographic Production Products.
Power Application & Mfg Co (PAMCO) (Wkers)	Casper, WY	12/02/91	11/11/91	26,631	Engine Generator & Compressors.
PPG Industries, Inc. (ABGW)	Greensburg, PA	12/02/91	11/22/91	26,632	Fabrication of Automobile Windshields.
Summit Timber (Wkrs)	Darrington, WA, PA	12/02/91	11/21/91	26,633	Dimensional Lumber and Timber.
Times Microwave Systems (Wkrs)	Wallingford, CT	12/02/91	11/20/91	26,634	Cable & Connectors.

[FR Doc. 91-30073 Filed 12-16-91; 8:45 am]
BILLING CODE 4510-30-M

[TA-W-26,298]

Flowline Division, New Castle, PA; Affirmative Determination Regarding Application for Reconsideration

On November 15, 1991 the company requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers at the subject firm. The Department's Negative Determination was issued on November 7, 1991 and published in the Federal Register on November 21, 1991 (56 FR 58711).

The company claims that the Department's customer survey was inadequate and submitted an additional list of customers.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 29th day of November 1991.

Robert O. Deslongchamps,

Director, Office of Legislation & Actuarial Services, Unemployment Insurance Service.

[FR Doc. 91-30071 Filed 12-16-91; 8:45 am]
BILLING CODE 4510-30-M

[TA-W-26,122]

The Merrow Machine Co.; Newington, CT; Negative Determination Regarding Application for Reconsideration

By an application dated November 5, 1991, one of the petitioners requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on October 10, 1991 and published in the Federal Register on October 29, 1991 (56 FR 55690).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Investigation findings show that the workers at Merrow Machine produce industrial sewing machines and parts.

The petitioner claims that the Department's survey was inadequate since it did not include sewing machine parts. The petitioner also claims that domestic garment manufacturers moved overseas and did not take their Merrow machines with them, thereby reducing the market for sewing machine parts.

Investigation findings show that nearly half of Merrow Machines' sales were for sewing machines parts. Although not specifically mentioned in the Department's denial notice, its survey was for sewing machines and sewing machine parts. None of the customers surveyed imported sewing machines or sewing machine parts. Customer comments show that the Merrow sewing machine was so designed that it had to use parts from The Merrow Machine Company. Accordingly, increased imports of other sewing machine parts would not provide a basis for a worker group certification.

Further, the decrease in the parts business because of the relocation of garment manufacturers overseas would not provide a basis for certification.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 29th day of November 1991.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services Unemployment Insurance Service.

[FR Doc. 91-30072 Filed 12-16-91; 8:45 am]
BILLING CODE 4510-30-M

Federal-State Unemployment Compensation Program Extended Benefits; Ending of Extended Benefit Period in the State of Puerto Rico

This notice announces the ending of the Extended Benefit Period in the State of Puerto Rico, effective on November 2, 1991.

Background

The Federal-State Extended Unemployment Compensation Act of 1970 (26 U.S.C. 3304 note) established the Extended Benefit Program as a part of the Federal-State Unemployment Compensation Program. Under the Extended Benefit Program, individuals who have exhausted their rights to regular unemployment benefits (UI) under permanent State (and Federal) unemployment compensation laws may be eligible, during and extended benefit period, to receive up to 13 weeks of extended unemployment benefits, at the same weekly rate of benefits as previously received under the State law. The Federal-State Extended Unemployment Compensation Act is implemented by State unemployment compensation laws and by part 615 of title 20 of the code of Federal Regulations (20 CFR part 615).

Extended Benefits are payable in a State during an Extended Benefit Period which is triggered "on" when the rate of insured unemployment in the State reached the State trigger rate set in the Act and the State law. During an Extended Benefit Period, individuals are eligible for a maximum of up to 13 weeks of benefits, but the total of

Extended Benefits and regular benefits together may not exceed 39 weeks.

The Act and the State unemployment compensation laws also provide that an Extended Benefit Period in a State will trigger "off" when the rate of insured unemployment in the State is no longer at the trigger rate set in the law. A benefit period actually terminates at the end of the third week after the week for which there is an off indicator, but not less than 13 weeks after the benefit period began.

An Extended Benefit Period commenced in the State of Puerto Rico on March 31, 1991, and has now triggered off.

Determination of an "Off" Indicator

The head of the employment security agency of the State named above has determined that the rate of insured unemployment in the State for the period consisting of the week ending on October 12, 1991, and the immediately preceding twelve weeks, fell below the State trigger rate, so that for that week there was an "off" indicator in the State.

Therefore, the Extended Benefit Period in the State terminated with the week ending November 2, 1991.

Information for Claimants

The State employment security agency will furnish a written notice to each individual who is filing claims for Extended Benefits of the ending of the Extended Benefit Period and its effect on the individual's right to Extended Benefits, 20 CFR 615.13(c)(4).

Persons who wish information about their rights to Extended Benefits in the State named above would contact the nearest State employment service office in their locality.

Signed at Washington, DC on December 12, 1991.

Roberts T. Jones,

Assistant Secretary of Labor.

[FR Doc. 91-30077 Filed 12-16-91; 8:45 am]

BILLING CODE 4510-30-M

Job Training Partnership Act: Announcement of Proposed Noncompetitive Grant Awards

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to Draketail Maritime, Ltd. of Shady Side, Maryland, for the provision of specialized services under the authority of the Job Training Partnership Act (JTPA).

DATES: It is anticipated that this grant award will be executed by January 6, 1992, and will be funded for twelve months. Submit comments by 4:45 p.m. (Eastern Time), on January 2, 1992.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C-4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Brenda Banks; Reference FR-DAA-005-91.

SUPPLEMENTARY INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the Draketail Maritime, Ltd. of Shady Side, Maryland. The Draketail Maritime Project is a pilot intergenerational, experiential-learning initiative designed to serve the student/family population of southern Anne Arundel county, along Maryland's western shore of the Chesapeake Bay. The key target population includes adolescent children ages ten to fifteen. The project's overall goals are to: improve student achievement; enhance the link between education and learning, and among school, work attitudes, habits and goals; and broaden the potential career landscape for young students. Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $98,500 for twelve months.

Signed at Washington, DC on December 9, 1991.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 91-30075 Filed 12-16-91; 8:45 am]

BILLING CODE 4510-30-M

Advisory Panel for the Dictionary of Occupational Titles (APDOT); Open Meeting

AGENCY: Employment and Training Administration, Labor.

SUMMARY: The Advisory Panel for the Dictionary of Occupational Titles (APDOT) was established in accordance with the Federal Advisory Committee Act (Pub. L. 92-463) on August 28, 1990.

The APDOT was established as part of the Secretary of Labor's Workforce Quality Agenda to improve the quality of the work force. The APDOT will assist the Department of Labor in meeting the goals of the Secretary's Agenda by providing a diversified range of user perspectives on the Dictionary of Occupational Titles (DOT). The DOT is a document which is used extensively in business, education and government. It defines, classifies and describes occupations in the labor market. A revised fourth edition of the DOT was published in September 1991. The APDOT will provide advice on a new, fifth edition.

The APDOT will report to and advise the Assistant Secretary for Employment and Training on the development, publication and dissemination of the DOT.

TIME: The meeting will begin at 8:30 a.m. on January 15, 1991, and adjourn at 2 p.m. that day.

PLACE: The U.S. Department of Labor, 200 Constitution Avenue NW., C-5515, Seminar Room 1A, Washington, DC 20210.

AGENDA: Matters to be considered as part of the agenda for the APDOT meeting include:

- Office of Personnel Management's Multi-Purpose Approach to Job Analysis.
- Fort Worth: Project C^3.
- Subcommittee on Purpose and Uses progress report.
- Subcommittee on Skills Issues progress report.

PUBLIC PARTICIPATION: The meeting will be open to the public. A half hour (8:45 a.m.-9:15 a.m.) will set aside for public comments. Individuals wishing to speak to the panel should call Dr. Marilyn Silver at 202-535-0161. Seating will be available for the public on a first-come, first-serve basis.

Individuals or organizations wishing to submit written statements should send 14 copies to Dr. Marilyn B. Silver, Executive Director, Advisory Panel for the Dictionary of Occupational Titles, room N4470, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Dr. Marilyn B. Silver, Executive Director, Advisory Panel for the Dictionary of Occupational Titles, room N4470, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202) 535-0161.

Signed at Washington, DC this 10th day of December 1991.

Roberts T. Jones,

Assistant Secretary for Employment and Training.

[FR Doc. 91-30074 Filed 12-16-91; 8:45 am]

BILLING CODE 4510-30-M

Attestations Filed by Facilities Using Nonimmigrant Aliens as Registered Nurses

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is publishing, for public information, a list of the following health care facilities which plan on employing nonimmigrant alien nurses. These organizations have attestations on file with DOL for that purpose.

ADDRESSES: Anyone interested in inspecting or reviewing the employer's attestation may do so at the employer's place of business.

Attestations and short supporting explanatory statements are also available for inspection in the Immigration Nursing Relief Act Public Disclosure Room, U.S. Employment Service, Employment and Training Administration, Department of Labor, room N4456, 200 Constitution Avenue, NW., Washington, DC 20210.

Any complaints regarding a particular attestation or a facility's activities under that attestation, shall be filed with a local office of the Wage and Hour Division of the Employment Standards Administration, U.S. Department of Labor. The address of such offices are found in many local telephone directories, or may be obtained by writing to the Wage and Hour Division, Employment Standards Administration, Department of Labor, room S3502, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT:

Regarding the Attestation Process

The Employment and Training Administration has established a voice-mail service for the H–1A nurse attestation process. Call Telephone Number: 202–535–0643 (this is not a toll-free number). At that number, a caller can:

(1) Listen to general information on the attestation process for H–1A nurses;

(2) Request a copy of the Department of Labor's regulations (20 CFR part 655, subparts D and E, and 29 CFR part 504, subparts D and E) for the attestation process for H–1A nurses, including a copy of the attestation form (form ETA 9029) and the instructions to the form;

(3) Listen to information on H–1A attestations filed within the preceding 30 days;

(4) Listen to information pertaining to public examination of H–1A attestations filed with the Department of Labor;

(5) Listen to information on filing a complaint with respect to a health care facility's H–1A attestation (however, see the telephone number regarding complaints, set forth below); and

(6) Request to speak to a Department of Labor employee regarding questions not answered by Nos. (1) through (4) above.

Regarding the Complaint Process

Questions regarding the complaint process for the H–1A nurse attestation program shall be made to the Chief, Farm Labor Program, Wage and Hour Division. Telephone: 202–523–7605 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Immigration and Nationality Act requires that a health care facility seeking to use nonimmigrant aliens as registered nurses first attest to the Department of Labor (DOL) that it is taking significant steps to develop, recruit and retain United States (U.S.) workers in the nursing profession. The law also requires that these foreign nurses will not adversely affect U.S. nurses and that the foreign nurses will be treated fairly. The facility's attestation must be on file with DOL before the Immigration and Naturalization Service will consider the facility's H–1A visa petitions for bringing nonimmigrant registered nurses to the United States. 26 U.S.C. 1101(a)(15)(H)(i) (a) and 1181(m). The regulations implementing the nursing attestation program are at 20 CFR part 655 and 29 CFR part 504, 55 FR 50500 (December 6, 1990). The Employment and Training Administration, pursuant to 20 CFR 655.310(c), is publishing the following list of facilities which have submitted attestations which have been accepted for filing.

The list of facilities is published so that U.S. registered nurses, and other persons and organizations can be aware of health care facilities that have requested foreign nurses for their staffs. If U.S. registered nurses or other persons wish to examine the attestation (on Form ETA 9029) and the supporting documentation, the facility is required to make the attestation and documentation available. Telephone numbers of the facilities' chief executive officers also are listed, to aid public inquiries. In addition, attestations and supporting short explanatory statements (but not the full supporting documentation) are available for inspection at the address for the Employment and Training Administration set forth in the **ADDRESSES** section of this notice.

If a person wishes to file a complaint regarding a particular attestation or a facility's activities under that attestation, such complaint must be filed at the address for the Wage and Hour Division of the Employment Standards Administration set forth in the **ADDRESSES** section of this notice.

Signed at Washington, DC, this 11 day of December 1991.

Robert J. Litman,

Acting Director, United States Employment Service.

Division of Foreign Labor Certifications Approved Attestations

[Nov. 1, 1991 to Nov. 30, 1991]

CEO-name/facility name/address	State	Approval date
Jeffrey P. Winter, Encino Hospital, 16237 Ventura Boulevard, Encino 91436, 818–995–5000.	California	11/14/91
Ms. Nini Bucoy, Comprehensive Nursing Service, 1941 O'Farrell St., San Mateo 94403, 415–571–5373.	California	11/15/91
Ms. Vicki L. Cummings, Sisters of Mercy, Marian Care Center, Bulingame 94010, 415–340–7429.	California	11/15/91
Mr. Gary Rapaport, Oak Valley Hospital District, 350 S. Oak Ave., Oakdale 95361, 209–847–3011.	California	11/22/91
William H. Comte, Doctors' Hospital, 5000 University Drive, Coral Gables 33146, 305–669–3401.	Florida	11/15/91
Mr. William T. Moore, Shallowford Hospital, 4575 N. Shallowford Rd., Dunwoody 30338, 404–454–2028.	Georgia	11/07/91
Mr. Frederick R. Bailey, N. Fulton Regional Hospital, 3000 Hospital Boulevard, Roswell 30076, 404–751–2656.	Georgia	11/15/91
Faye Nazon, Conjeunaze Nursing Center, 3311 S. Michigan, Chicago 60616, 312–326–5700.	Illinois	11/15/91
Mr. John Samatas, Lexington Health Care Center, of Chicago Ridge, Inc., Chicago Ridge 60415, 708–495–1700.	Illinois	11/20/91

DIVISION OF FOREIGN LABOR CERTIFICATIONS APPROVED ATTESTATIONS—Continued

[Nov. 1, 1991 to Nov. 30, 1991]

CEO-name/facility name/address	State	Approval date
Joseph O'Grady-Peyton, O'Grady-Peyton Int'l USA Inc., 651 Boylston Street, Boston 02116, 617-262-3533.	Massachusetts	11/21/91
Mr. Robert E. Pezzoli, St. Agenes Hospital of the City of Baltimore, Baltimore 21229, 410-368-6000.	Maryland	11/22/91
Ms. Gladys A. Sullivan, Village North Woods, 9500 Bellefontaine Road, Bellfont Neighbors 63137, 314-868-1400.	Missouri	11/07/91
Ms. Ronnette Cox, Convalescent Center of Enfiel, 208 Cary Street, Enfield 27823, 919-445-2111.	North Carolina	11/07/91
Ms. Dolores Turco, Lincoln Park Nursing Center, 499-521 Pine Brook Road, Lincoln Park 07035, 201-696-3300.	New Jersey	11/07/91
Leonora Pilao-Dwyer, King David Care Center of Atlantic City, Atlantic City 08401, 609-344-2181.	New Jersey	11/15/91
Daniel J. Moles, Ashbrook Nursing Home, 1610 Raritan Road, Scotch Plains 07076, 908-889-5500.	New Jersey	11/21/91
Sr. Paola Canziani, Casa Angelica, 5629 Isleta Blvd SW, Albuquerque 87105, 505-877-5763.	New Mexico	11/21/91
Ms. Phyllis Schindler, Long Island Nursing Home, 144-61 38th Avenue, Flushing 11354, 718-939-7500.	New York	11/07/91
Gene Rose, Queens Artificial Kidney Center, Jackson Heights 11372, 718-651-9700.	New York	11/21/91
Sister Mary Blandine, Saint Francis Hospital, Inc., 6161 S. Yale Ave., Tulsa 74136, 918-494-2200.	Oklahoma	11/20/91

DIVISION OF FOREIGN LABOR CERTIFICATIONS APPROVED ATTESTATIONS—Continued

[Nov. 1, 1991 to Nov. 30, 1991]

CEO-name/facility name/address	State	Approval date
Ms. Vickie H. Tears, Good Samaritan Convalescent Center, Antioch 37013, 615-731-7130.	Tennessee	11/15/91
Larry F. Parsons, Wilbarger General Hospital, 920 Hillcrest Drive, Vernon 76384, 817-552-9351.	Texas	11/14/91
Judith G. Novak, Woman's & Medical Center Hospital, Houston 77054, 713-790-8101.	Texas	11/15/91
Nedro G. Parker, Health Network International, 4506 La Branch, Houston 77004, 713-522-2443.	Texas	11/22/91
David S. Dunham, Southside Regional Medical Center, Petersburg 23803, 804-862-5768.	Virginia	11/15/91

Total Attestations: 26.

[FR Doc. 91-30082 Filed 12-16-91; 8:45 am]

BILLING CODE 4510-30-M

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of mandatory safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. L. V. Coal Company

[Docket No. M-91-107-C]

L. V. Coal Company, RD 1, Box 929, Ashland, Pennsylvania 17921 has filed a petition to modify the application of 30 CFR 75.301 (air quality, quantity and velocity) to its No. 4 Slope (I.D. No. 36-08014) located in Schuylkill County, Pennsylvania. The petitioner requests a modification to require the minimum quantity of air reaching the working face be 1,500 cubic feet a minute (cfm), reaching the last open crosscut in any pair or set of developing entries be 5,000 cfm, and reaching the intake end of a pillar line be 5,000 cfm.

2. Consolidation Coal Company

[Docket No. M-91-108-C]

Consolidation Coal Company, Consol Plaza, Pittsburgh, Pennsylvania 15241-1421 has filed a petition to modify the application of 30 CFR 75.1002 (location of trolley wires, trolley feeder wires, high-voltage cables and transformers) to its Dilworth Mine (I.D. No. 36-04281) located in Greene County, Pennsylvania. The petitioner proposes to use high-voltage cables inby the last open crosscut to power the longwall.

3. Eagle Nest, Inc.

[Docket No. M-91-109-C]

Eagle Nest, Inc., P.O. Box 270, Van, West Virginia 25206 has filed a petition to modify the application of 30 CFR 75.1700 (oil and gas wells) to its No. 132 Mine (I.D. No. 46-04789); its No. 131 Mine (I.D. No. 46-01268); and its Eagle Mine (I.D. No. 46-07711) all located in Boone County, West Virginia. The petitioner proposes to plug and mine through oil and gas wells.

4. Consolidation Coal Company

[Docket No. M-91-110-C]

Consolidation Coal Company, Consol Plaza, Pittsburgh, Pennsylvania 15241-1421 has filed a petition to modify the application of 30 CFR 75.305 (weekly examinations for hazardous conditions) to its Ireland Mine (I.D. No. 46-10438) located in Marshall County, West Virginia. Due to deteriorating roof conditions, the petitioner proposes to establish evaluation points to monitor the hazardous conditions.

5. Island Creek Coal Company

[Docket No. M-91-111-C]

Island Creek Coal Company, P.O. Box 11430, Lexington, Kentucky 40575-1430 has filed a petition to modify the application of 30 CFR 75.1103-4 (automatic fire sensor and warning device systems); installation; minimum requirements) to its Hamilton No. 2 Mine (I.D. No. 15-02706) located in Union County, Kentucky. The petitioner proposes to use belt air to ventilate the working face and remove restrictions on the velocity of air in the belt entries, and use a low-level carbon monoxide detection system to monitor the air in the belt entries.

6. Island Creek Coal Company

[Docket No. M-91-112-C]

Island Creek Coal Company, P.O. Box 11430, Lexington, Kentucky 40575-1430 has filed a petition to modify the application of 30 CFR 75.326 (aircourses

and belt haulage entries); to its Hamilton No. 2 Mine (I.D. No. 15–02706) located in Union County, Kentucky. The petitioner proposes to use belt air to ventilate the working face and remove restrictions on the velocity of air, and use a low-level carbon monoxide detection system to monitor the air in the belt entries.

7. Wilgar Land Company

[Docket No. M–91–113–C]

Wilgar Land Company, P.O. Box 266, Robinson Creek, Kentucky 41560 has filed a petition to modify the application of 30 CFR 75.1710 (canopies or cabs; electric face equipment) to its No. 3 Mine (I.D. No. 15–10396) located in Pike County, Kentucky. The petitioner states that the use of canopies on the S&S supply scoop would result in a safety hazard to the equipment operator.

8. Clinchfield Coal Company

[Docket No. M–91–114–C]

Clinchfield Coal Company, P.O. Box 4000, Lebanon, Virginia 24266 has filed a petition to modify the application of 30 CFR 75.1105 (housing of underground transformer stations, battery-charging stations; substations, compressor stations, shops, and permanent pumps) to its McClure No. 2 Mine (I.D. No. 44–04946) located in Dickenson County, Virginia. The petitioner proposes to use a carbon monoxide detection system to monitor electrical equipment instead of ventilating the equipment directly to the return.

9. Clinchfield Coal Company

[Docket No. M–91–115–C]

Clinchfield Coal Company, P.O. Box 4000, Lebanon, Virginia 24266 has filed a petition to modify the application of 30 CFR 75.326 (aircourse and belt-haulage entries) to its McClure No. 2 Mine (I.D. No. 44–04946) located in Dickenson County, Virginia. The petitioner proposes to use belt air to ventilate active working places, and install a low-level carbon monoxide detection system in all belt entries used as intake aircourses.

10. Shell Mining Company

[Docket No. M–91–116–C]

Shell Mining Company, P.O. Box 2906, Houston, Texas 77252–2906 has filed a petition to modify the application of 30 CFR 77.900 (low- and medium-voltage circuits serving portable or mobile three-phase alternating current equipment; circuit breakers) to its North Rochelle Coal Mine (I.D. No. 48–01355) located in Campbell County, Wyoming. The petitioner proposes to use an automatic reset circuit breaker to supply power to electrical equipment instead of using a manual reset breaker.

11. Cyprus Thompson Creek Mining Company

[Docket No. M–91–20–C]

Cyprus Thompson Creek Mining Company, 9100 East Mineral Circle, Englewood, Colorado 80112 has filed a petition to modify the application of 30 CFR 56.6309 (fuel oil requirements for ANFO) to its Thompson Creek Mining (I.D. No. 10–00531) located in Custer County, Idaho. The petitioner proposes to design and construct an oil recycling system that filters used oil, and blends the recycled product with fuel oil for use in blasting.

Request for Comments

Persons interested in these petitions may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 16, 1991. Copies of these petition are available for inspection at that address.

Dated: December 11, 1991.

Patricia W. Silver,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 91–30076 Filed 12–16–91; 8:45 am]

BILLING CODE 4510–43–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–277, 50–278, 50–352 and 50–353]

Philadelphia Electric Co; Public Service Electric and Gas Co.; Delmarva Power and Light Co; Atlantic City Electric Co.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering issuance of an exemption to Philadelphia Electric Company, et. al. (PECo, the licensees), for operation of the Peach Bottom Atomic Power Station, Units 2 and 3, located in York County, Pennsylvania, and the Limerick Generating Station, Units 1 and 2, located in Montgomery and Chester Counties, Pennsylvania.

Environmental Assessment

Identification of Proposed Action

The proposed exemption would 1) grant a one-time schedular exemption to eight (8) Senior Reactor Operators limited to fuel handling (LSROs) to permit them to take their first annual requalification operating test during January 1992 instead of the end of 1991.

The Need for the Proposed Action

By letter dated October 18, 1991, the licensee requested an exemption, in accordance with 10 CFR 55.11 from the requirements of 10 CFR 55.59(a)(2) and 10 CFR 55.59(c)(4)(i) related to annual requalification operating tests for LSROs. Pursuant to 10 CFR 55.53(h) a licensee, as a condition of the license, shall complete a requalification program as described by 10 CFR 55.59. In 10 CFR 55.59(c)(4)(i), the requalification program must include annual operating tests, and 10 CFR 55.59(a)(2) stipulates that each licensee shall pass an annual operating test.

NRC Generic Letter (GL) No. 89–03, "Operator Licensing National Examination Schedule," issued March 24, 1989, specified two examination months for each facility during which operator licensing examinations would be conducted each year. The purpose of the national examination schedule is to provide a consistent time period for conducting the examinations at each facility so that the facility can establish a standard schedule for conducting the required licensed operator training, and so that the NRC can schedule the resources required for conducting the examinations. The national examination schedule months for LGS, Units 1 and 2, are January and July. The scheduled months for PBAPS are February and August. PECo is requesting, on behalf of the licensed LSROs, a one-time schedular exemption from the requirements of 10 CFR 55.59(a)(2) with regard to each individual licensed LSRO to conduct the first annual requalification operating test for the multi-site licensed LSROs in January 1992 in conformance with the national examination schedule for LGS instead of the end of 1991. By letter dated October 18, 1991, from R.J. Conte, NRC, Region I, to D.M. Smith, PECo, the NRC confirmed that arrangements have been made for administration of fuel handling licensing examinations at LGS, for both Limerick and Peach Bottom, during the week of January 13, 1992.

Environmental Impacts of the Proposed Action

The proposed exemption from 10 CFR 55.59(c)(4)(i) and 10 CFR 55.59(a)(2) will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant cumulative radiation exposure. Accordingly, the Commission concludes that these proposed exemptions would result in no significant radiological environmental impact. Additional, it does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant impacts associated with the proposed exemptions.

Alternative to the Proposed Action

Since the Commission concluded that there are no significant environmental affects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

The principal alternative would be to deny the requested exemptions. This would not reduce environmental impacts of plant operation and would result in reduced operational flexibility.

Alternative Use of Resources

This proposed action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Limerick Generating Station, dated April 1984 or the Final Environmental Statement for the Peach Bottom Atomic Power Station, dated April 1973.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of no Significant Impact

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

The Commission has determined not to prepare an environmental impact statement for the proposed exemptions.

For further details with respect to this action, see the request for exemption dated October 18, 1991, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, Lower Level, 2120 L Street, NW., Washington, DC, 20555, at the Limerick Local Public Document Room located at Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464 and at the Peach Bottom Local Public Document Room located at Government Publications Section, State Library of Pennsylvania, (Regional Depository) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Dated at Rockville, Maryland this 10th day of December 1991.

For the Nuclear Regulatory Commission.

Charles L. Miller,

Director, Project Directorate I-2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 91-30059 Filed 12-16-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-260]

Tennessee Valley Authority; Consideration of Issuance of Amendment to Facility Operating License, Proposed no Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-52 issued to the Tennessee Valley Authority (TVA) for operation of the Browns Ferry Nuclear Plant (BFNP), Unit 2 located in Limestone County, Alabama.

The proposed amendment would revise the Limiting Conditions for Operation (LCO) of the Technical Specifications (TS) for the Containment Atmosphere Dilution (CAD) System. More specifically, the LCO requirements of TS 3.7.G and Table 3.2.F would be temporarily changed (i.e., until the next refueling outage) to allow for extended plant operation with only one of two CAD systems operable.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

As required by 10 CFR 50.91(a), TVA has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment will not affect the probability of occurrence (or consequences) of a previously analyzed accident. The main function of the CAD system is to mitigate the effects of an accident by limiting the concentration of oxygen in the containment atmosphere after an accident has occurred. The consequences of a (an) accident are not significantly affected because the single train CAD system allowed by this change is not relied upon to mitigate an accident. Conservative analysis has demonstrated that processes within the containment after an accident will not generate sufficient oxygen to produce a combustible mixture and the CAD function will not be needed. (A single train is capable of performing 100 percent of the CAD systems safety functions. Furthermore, offsite supplies exist to supplement the remaining train as necessary).

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The CAD system is not a factor in normal plant operation and is mainly used after a postulated loss of coolant accident to control combustible gas inside the primary containment, as a backup pneumatic supply to the torus to reactor building vacuum breakers or to provide backup pneumatic supply to operate main steam relief valves during events beyond-design-basis. The availability of the backup pneumatic supply is not addressed in technical specifications and not directly affected by the proposed amendment. (Furthermore, each CAD system train is fully capable of performing this system's safety function. Loss of one train does not initiate a new or different kind of accident, and if a redundant nitrogen source becomes necessary, time exists to locate offsite supplies).

3. The proposed amendment does not involve a significant reduction in a margin of safety. The affected safety function of the CAD system to limit combustible gas mixture inside the primary containment is not relied upon during post accident. The containment is inerted with nitrogen during normal operation and a more recent analysis documented in General Electric NEDO 22155 demonstrates that generation of oxygen within the containment after an accident is not sufficient to produce a

combustible mixture (greater than five percent). (Furthermore, should a redundant source of nitrogen for the CAD system be required to perform its safety function, offsite commercial supplies are available within 12 hours).

The NRC staff has reviewed the licensee's analysis and concluded that the three standards of 10 CFR 50.92(c) appear to be satisfied. Therefore, based on the above considerations, the Commission has made a proposed determination that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received with thirty (30) days after the date of publication of this notice will be considered in making any final determination. The commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By January 16, 1992, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Athens Public Library on South Street in Athens, Alabama 35611. If a request for a hearing or a petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent to the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter or the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

No later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform

the Commission by a toll-free telephone call to Western Union at 1–(800) 325–6000 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Frederick J. Hebdon, Director (petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice). A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the General Counsel for TVA at ET 11H, 400 West Summit Hill Drive, Knoxville, Tennessee 37902, attorney for the licensee.

Nontimely filing of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated December 6, 1991, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Athens Public Library on South Street in Athens, Alabama 35611.

Dated at Rockville, Maryland, this 11th day of December 1991.

For the Nuclear Regulatory Commission.

Thierry M. Ross,

Senior Project Manager, Project Directorate II–4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 91–30058 Filed 12–16–91; 8:45 am]

BILLING CODE 7590–01–M

State of Maine: Staff Assessment of Proposed Agreement Between the Nuclear Regulatory Commission and the State of Maine

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of proposed agreement with the state of Maine.

SUMMARY: The U.S. Nuclear Regulatory Commission is publishing for public comment the NRC staff assessment of a proposed agreement received from the Governor of the State of Maine for the assumption of certain of the Commission's regulatory authority pursuant to section 274 of the Atomic Energy Act of 1954, as amended. Comments are requested on the public health and safety aspects of the proposal.

Exemptions from the Commission's regulatory authority, which would implement this proposed agreement, have been published in the **Federal Register** and codified as part 150 of the Commission's regulations in title 10 of the Code of Federal Regulations.

DATES: Comments must be received on or before January 2, 1992.

ADDRESSES: Submit comments to the Chief, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, Washington, DC 20555. Comments may also be delivered to 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Monday through Friday. Copies of comments received by NRC may be examined at the NRC. Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. A copy of the proposed agreement, program narrative, including the referenced appendices, applicable State legislation and Maine regulations, is available for public inspection in the NRC's Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC, telephone: (202) 634–3273.

FOR FURTHER INFORMATION CONTACT: Kathleen N. Schneider, State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301–492–0320.

SUPPLEMENTARY INFORMATION: Assessment of Proposed Maine Program to Regulate Certain Radioactive Materials pursuant to section 274 of the Atomic Energy Act of 1954, as amended (the Act).

The Commission has received a proposal from the Governor of Maine for the State to enter into an agreement with the NRC whereby the NRC would relinquish and the State would assume certain regulatory authority pursuant to section 274 of the Act.

Section 274e of the Act requires that the terms of the proposed agreement be published for public comment once each week for four consecutive weeks. Accordingly, this notice will be published four times in the **Federal Register**.

I. Background

A. Section 274 of the Act provides a mechanism whereby the NRC may transfer to the States certain regulatory authority over agreement materials [1] when a State desires to assume this authority and the Governor certifies that the State has an adequate regulatory program, and when the Commission finds that the State's program is compatible with that of the NRC and is adequate to protect the public health and safety. Section 274g directs the Commission to cooperate with the States in the formulation of standards for protection against radiation hazards to assure that State and Commission programs for radiation protection will be coordinated and compatible. Further, section 274j provides that the Commission shall periodically review such agreements and actions taken by the States under the agreements to ensure compliance with the provisions of this section.

B. In a letter dated March 5, 1990, Governor John P. McKernan, Jr. of the State of Maine requested that the Commission enter into an agreement with the State pursuant to section 274 of the Act. The Governor certified that the State of Maine has a program for control of radiation hazards which is adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State of Maine desires to assume regulatory responsibility for such materials. The text of the proposed agreement is shown in Appendix A to this document.

The specific authority requested is for (1) byproduct material as defined in section 11e.(1) of the Act, (2) source material, and (3) special nuclear material in quantities not sufficient to form a critical mass. The State does not wish to assume authority over (1) land disposal of source, byproduct and special nuclear material received from other persons; and (2) uranium recovery activities (byproduct material as defined in section 11e.(2)). The State, however, reserves the right to apply at a future date to NRC for an amended agreement to assume authority in these areas. The nine articles of the proposed agreement—

Lists the materials covered by the agreement.

Lists the Commission's continued authority and responsibility for certain activities.

Allows for future amendment of the agreement.

Allows for certain regulatory changes by the Commission.

References the continued authority of the Commission for common defense and security for safeguard purposes.

[1] A byproduct materials as defined in 11e.(1), B. Byproduct materials as defined in 11e.(2), C. Source materials; and D. Special nuclear materials in quantities not sufficient to form a critical mass.

Pledges the best efforts of the Commission and the State to achieve coordinated and compatible programs.
Recognizes reciprocity of licenses issued by the respective agencies.
Sets forth criteria for termination or suspension of the agreement.
Specifies the effective date of the agreement.

C. Maine Radiation Protection Act, sections 671 through 690, the enabling statute for the Maine Department of Human Services, authorizes the Department to issue licenses to, and perform inspections of, users of radioactive materials under the proposed agreement and otherwise carry out a total radiation control program. Maine regulations for radiation protection were adopted on January 1, 1986, with revisions dated January 1, 1988 and December 1, 1990, under authority of the enabling statute and provide standards, licensing, inspection, enforcement and administrative procedures for agreement and non-agreement materials. In addition, editorial revisions recommended by NRC are presently under consideration in Maine and are expected to be finalized in November 1991. Pursuant to Maine's regulations, section C.19, the regulations will apply to agreement materials on the effective date of the agreement. In addition to the material covered under the proposed agreement, the regulations provide for the State to license and inspect users of naturally-occurring and accelerator-produced radioactive materials.

D. The NRC staff assessment finds the proposed Maine program will provide adequately for public health and safety.

II. NRC Staff Assessment of the Proposed Maine Program for Control of Agreement Materials

Reference: Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement.[2]

Objectives

1. *Protection.* A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.

Based upon the analysis of the State's proposed regulatory program, the staff believes the Maine proposed regulatory program for agreement materials is adequately designed to protect the health and safety of the public against radiation hazards.

Reference: Maine Program Statement, Application for Agreement State Status.

Radiation Protection Standards

2. *Standards.* The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass.

Statutory authority to formulate and promulgate rules for controlling exposure to sources of radiation is contained in the enabling statute. In accordance with that authority, the State adopted radiation control regulations on January 1, 1986, and with revisions dated January 1, 1988, and December 1, 1990, which include radiation protection standards which would apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass upon the effective date of an agreement between the State and the Commission pursuant to Section 274b of the Atomic Energy Act of 1954, as amended. In addition, editorial revisions recommended by NRC are presently under consideration by the State and are expected to be finalized in November 1991.

Reference: State of Maine Rules Relating to Radiation Protection, parts A, B, C, D, E, G, J, K, L, Letter dated October 15, 1991.

3. *Uniformity in Radiation Standards.* It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR part 20 of the NRC regulations based on officially approved radiation protection guides.

Technical definitions and terminology contained in the Maine Radiation Control Regulations including those related to units of measurement and radiation doses are uniform with those contained in 10 CFR part 20.

Reference: State of Maine Rules Relating to Radiation Protection, Sections A.2, D.2, E.3, G.2, K.3, L.2.

4. *Total Occupational Radiation Exposure.* The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.

The Maine regulations cover all sources of radiation within the State's jurisdiction and provide for consideration of the total radiation exposure of individuals from all sources of radiation in the possession of a licensee or registrant.

Reference: State of Maine Rules Relating to Radiation Protection, Sections D.2 to D.7.

5. *Surveys, Monitoring.* Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.

The Maine requirements for surveys to evaluate potential exposures from sources of radiation and the personnel monitoring requirements are uniform with those contained in 10 CFR part 20.

References: State of Maine Rules Relating to Radiation Protection, Sections D.9, D.10 and D.15.

6. *Labels, Signs, Symbols.* It is desirable to achieve uniformity in labels, signs, and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.

The prescribed radiation labels, signs and symbols are uniform with those contained in 10 CFR parts 20, 30 through 32 and 34. The Maine posting requirements are also uniform with those of 10 CFR part 20.

References: State of Maine Rules Relating to Radiation Protection, Sections C.6.E, C.6.F, C.11.D, D.11, and D.12.

7. *Instruction.* Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19.16 and to be represented during inspections as specified in 10 CFR 19.14.

The Maine regulations contain requirements for instructions and notices to workers that are uniform with those of 10 CFR part 19.

Reference: State of Maine Rules Relating to Radiation Protection, Section J.

8. *Storage.* Licensed radioactive material in storage shall be secured against unauthorized removal.

The Maine regulations contain a requirement for security of stored radioactive material.

Reference: State of Maine Rules Relating to Radiation Protection, Section D.14.

9. *Radioactive Waste Disposal.* (a) Waste disposal by material users. The standards for the disposal of radioactive

[2] NRC Statement of Policy published in the Federal Register January 23, 1981 (46 FR 7540–7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register July 21, 1983 (48 FR 33376).

materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority.

Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR part 20.

The waste disposal standards shall include a waste classification scheme and provisions for waste form, application to waste generators, that is equivalent to that contained in 10 CFR part 61.

(b) Land disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97–425).

The Maine regulations contain provisions relating to the disposal of radioactive materials into the air, water and sewer, and burial in soil which are essentially uniform with those of 10 CFR part 20. Waste transfer and manifest system requirements for transfer of waste for ultimate disposal at a land disposal facility are included in the Maine regulations. The waste disposal requirements include a waste classification scheme and provisions for waste form equivalent to that in 10 CFR part 61.

Maine does not plan on seeking authority for the regulation of land disposal of source, byproduct and special nuclear material received from other persons.

References: State of Maine Rules Relating to Radiation Protection, Sections D.7, and D.16 to D.26.

10. *Regulations Governing Shipment of Radioactive Materials.* The State shall to the extent of its jurisdiction promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR part 71.

The Maine regulations are uniform with those contained in NRC regulations 10 CFR part 71.

References: State of Maine Rules Relating to Radiation Protection Section L.

11. *Records and Reports.* The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The Maine regulations require the following records and reports of the licensees and registrants:

(a) Records covering personnel radiation exposures, radiation surveys, and disposals of materials.

(b) Records of receipt and transfer of materials.

(c) Reports concerning incidents involving radioactive materials.

(d) Reports to former employees of their radiation exposure.

(e) Reports to employees of their annual radiation exposure.

(f) Reports to employees of radiation exposure in excess of prescribed limits.

Reference: State of Maine Rules Relating to Radiation Protection Sections A.4, D.27, D.29, D.30, and J.4.

12. *Additional Requirements and Exemptions.* Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.

The Maine Radiation Control Program is authorized to impose upon any licensee or registrant by rule, regulation, or order such requirements in addition to those established in the regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

Reference: State of Maine Rules Relating to Radiation Protection Section A.7.

The Department may also grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

Reference: State of Maine Rules Relating to Radiation Protection Section A.3.

Prior Evaluation of Uses of Radioactive Materials

13. *Prior Evaluation of Hazards and Uses, Exceptions.* In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards and the capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the possessor and user. These categories fall into two groups—those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating each specific use.

Prior to the issuance of a specific license for the use of radioactive materials, the Maine Radiation Control Program will require the submission of information on, and will make an evaluation of, the potential hazards of such uses, and the capability of the applicant.

References: State of Maine Rules Relating to Radiation Protection

Sections C.7 and C.17 and the Maine Program Statement.

Provision is made for the issuance of general licenses for byproduct, source and special nuclear materials in situations where prior evaluation of the licensee's qualifications, facilities, equipment and procedures is not required. The regulations grant general licenses under the same circumstances as those under which general licenses are granted in the Commission's regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.5 and C.6.

The Maine regulations contain provisions for exempting of certain source and other radioactive materials and devices containing radioactive materials. These exemptions, for materials covered by the agreement, are the same as those granted by NRC regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.2 and C.3.

14. *Evaluation Criteria.* In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be consistent with NRC licensing and regulatory guides for various categories of licensed activities.

In evaluating a proposal to use agreement materials, the Maine Radiation Control Program will determine that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with the regulations in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property; and

(3) The issuance of the license will not be inimical to the health and safety of the public.

Other special requirements for the issuance of specific licenses are contained in the regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.8 to C.11 and the Maine Program Statement.

15. *Human Use.* The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

The Marine regulations require that the use of radioactive materials (including sealed sources) on or in humans shall be by a physician having substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.

Reference: State of Maine Rules Relating to Radiation Protection Sections G.66 to G.76.

Inspection

16. *Purpose, Frequency.* The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance.

Maine materials licensees will be subject to inspection by Radiation Control Program, Division of Health Engineering, the Department of Human Services. Upon instruction from the Department, licensees shall perform or permit the Department to perform any reasonable test and survey the Department considers appropriate or necessary. The frequency of inspections is dependent upon the type and scope of the licensed activities and will be at least as frequent as inspections of similar licensees by NRC. Generally, inspections will be unannounced.

References: State of Maine Rules Relating to Radiation Protection Sections A.5, A.6, A.7 and J.5.A; Maine Program Statement.

17. *Inspections Compulsory.* Licensees shall be under obligation by law to provide access to inspectors.

Maine regulations state that licensees shall afford the Department, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

Reference: State of Maine Rules Relating to Radiation Protection Section A.5.

18. *Notification of Results of Inspection.* Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.

Following Radiation Control Program inspections, each licensee will be notified in writing of the results of the inspection. The letters and written notices indicate if the licensee is in compliance and if not, list the areas of noncompliance.

Reference: Maine Program Statement.

Enforcement

19. *Enforcement:* Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties.

The Maine Radiation Control Program is equipped with the necessary powers for prompt enforcement of the regulations. Where conditions exist that create a clear presence of a hazard to the public health that requires immediate action to protect human health and safety, Maine may issue orders to reduce, discontinue or eliminate such conditions. The Radiation Control Program actions may also include impounding of radioactive material, imposition of a civil penalty, revocation of a license, and requesting the State Attorney General to seek injunctions and convictions for criminal violations.

References: State of Maine Rules Relating to Radiation Protection Sections A.7, A.8, A.9, part B and C.22; Maine Radiation Protection Act Sections 688 and 690; Maine Program Statement.

Personnel

20. *Qualifications of Regulatory and Inspection Personnel.* The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspection of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments—their selection, use, and calibration—laboratory design, contamination

control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology, and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training in radiation protection.

It is recognized that there will also be persons performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These persons should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint; for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

(a) Number of personnel. There are approximately 110 NRC specific licenses in the State of Maine. Under the proposed agreement, the State would assume responsibility for about 105 of these licenses. The Division of Health Engineering is currently staffed with 8 professional persons.

Donald Hoxie—Director, Division of Health Engineering. Responsible for the overall supervision of four Statewide regulatory programs, including the Radiological Health Program.

Wallace Hinckley—Assistant Director of Health Engineering. Responsible as Assistant Director for the overall supervision of four Statewide regulatory programs, including the Radiation Control Program.

Wellington Clough Toppan, Jr.—Manager, Radiation Control Program. Responsible for overall supervision of the Radiation Control Program, which regulates x-ray equipment and radionuclide users and conducts environmental monitoring of nuclear power facilities.

Robert Schell—Nuclear Engineering Specialist, Radiation Control Program. Responsible for environmental surveillance of and emergency planning for Maine Yankee Atomic Power Company.

David Breau—Sanitary Engineer II, Drinking Water Program. Responsible for review and approval of engineering plans for water treatment facilities. Backup staff available to the Radiation Control Program.

Linda A. Plausquellic—Radiation Specialist, Radiation Control Program. Performs compliance inspections and registration for x-ray machines. Assists in radioactive materials licensing program.

Jay Carl Hyland—Health Physicist, Radiological Health Program. Responsible for radioactive materials licensing and inspection program.

Cheryl Baker—Chemist II. Responsible for implementation of all radiological testing.

(b) Training. The academic and specialized short course training for those persons involved in the administration, licensing and inspection of the radiation control program is shown below:

Donald C. Hoxie—B.S. Chemical Engineering, University of Maine, M.S. Radiological Health, Rutgers University.
- U.S. Public Health Service, Basic Radiological Health. Two week course in 1960.
- Oak Ridge Associated Universities, Health Physics Course. A 10-week course ending May 1961.
- Brookhaven National Laboratory, Health Physics Training. A 4-week course ending September 1966.
- Conference of Radiation Control Program Directors, Training for Radiation Therapy Inspections. November 3–25, 1984.
- Conference of Radiation Control Program Directors, Training for Radon Control. November 28–29, 1986.

Wallace W. Hinckley—B.S., Civil Engineering, University of Maine.
- University of Oklahoma, NIOSH Course. Safety and Health. January 8 to March 30, 1973.
- Federal and Emergency Management Agency. Radiological Emergency Response Planning. 1974 and 1978.
- Federal Emergency Management Agency. Basic Radiological Defense Officers Course. Course I, March 7, 1975. Course II, March 14, 1975.
- Harvard University, Basic Radiation Protection. April 4–8, 1977.
- Harvard University, Environmental Surveillance. May 16–20, 1977.
- Harvard University, Planning for Nuclear Emergencies. June 13–17, 1977.
- U.S. Nuclear Regulatory Commission, Oak Ridge Associated Universities, Health Physics and Radiation Protection. A 5-week course ending April 14, 1978.
- Federal Emergency Management Agency, Radiological Emergency Response Course. August 19–29, 1980.
- Federal Emergency Management Agency, Radiological Accident Assessment Course. February 2–6,

1981.

Wellington Clough Toppan, Jr.—B.S., Civil Engineering, Norwich University, M.S., Environmental Engineering, Clarkson College of Technology, M.P.A., Public Administration, University of Maine at Orono.

Federal Emergency Management Agency, Radiological Emergency Response Planning. May 18–22, 1981.

Federal Emergency Management Agency, Basic Radiological Defense Officers. September 8–11, 1981.

Federal Emergency Management Agency, Radiological Accident Assessment. August 23–27, 1982.

New England Radiological Health Committee, Radiological Laboratory Workshop I. April 24–25, 1984.

Federal Emergency Management Agency, Radiological Emergency Response. September 12–21, 1984.

Conference of Radiation Control Program Directors, Training for Radiation Therapy Inspections. October 23–25, 1984.

U.S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. February 3 to March 8, 1985.

New England Radiological Health Committee, Radiological Laboratory Workshop II. April 30 to May 2, 1985.

U.S. Nuclear Regulatory Commission, Introduction to Licensing Practices and Procedures. September 23–27, 1985.

Conference of Radiation Control Program Directors, Health Issues of Non Ionizing Radiation. October 29–30, 1985.

U.S. Environmental Protection, Indoor Radon Workshop. January 21–23, 1986.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 15–20, 1987.

U.S. Nuclear Regulatory Commission, Pressurized Water Reactor Technology. April 28 to May 1, 1987.

U.S. Nuclear Regulatory Commission, Nuclear Transportation Course. August 17–21, 1987.

Southern Maine Vocational Technical School, Radon Mitigation Course. April 12–14, 1988.

Robert J. Schell—B.S., Bioengineering, University of Illinois.

United States Air Force Course, Bioenvironmental Engineering. March 18 to June 21, 1985.

Federal Emergency Management Agency, Radiological Emergency Response. October 16–26, 1985.

U.S. Nuclear Regulatory Commission, Introduction to Health Physics. February 10 to March 14, 1986.

Federal Emergency Management Agency, Radiological Response Planning. June 2–6, 1986.

Federal Emergency Management Agency, Radiologic Accident Assessment. July 14–18, 1986.

University of Massachusetts Medical Center, Medical X-Ray Inspection. August 19–22, 1986.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. September 8–12, 1986.

U.S. Nuclear Regulatory Commission, PWR Technology. February 23–27, 1987.

U.S. Nuclear Regulatory Commission, CE Technology. June 1–12, 1987.

U.S. Nuclear Regulatory Commission, Inspection Procedures. June 6–10, 1988.

U.S. Nuclear Regulatory Commission, Safety Aspects of Industrial Radiography. August 1–5, 1991.

Federal Emergency Management Agency, Advanced Radiological Accident Assessment. January 23–27, 1989.

David P. Breau—B.S., Civil Engineering, University of Maine at Orono.

Federal Emergency Management Agency, Basic Radiological Defense Officers Course. September 8–11, 1981.

Federal Emergency Management Agency, Nuclear Power Plant Offsite Accident Assessment Course. May 13–17, 1985.

U.S. Nuclear Regulatory Commission, Reactor Theory Operations and Emergency Planning. June 18–21, 1985.

Federal Emergency Management Agency, X-Ray Training. October 16–17, 1985.

Conference of Radiation Control Program Directors, Health Issues of Non Ionizing Radiation. October 29–30, 1985.

Federal Emergency Management Agency, Radiological Emergency Response Course. August 20–29, 1986.

U.S. Nuclear Regulatory Commission, Medical Use of Radionuclides. September 8–12, 1986.

U.S. Nuclear Regulatory Commission, Inspection Procedures Course. September 15–19, 1986.

U.S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. July 20 to August 21, 1987.

U.S. Nuclear Regulatory Commission, Licensing and Practices and Procedures. September 21–25, 1987.

Linda A. Plusquellic—Maine Central Institute, The John Hopkins Hospital School of Radiologic Technology, University of Maine, working toward B.S., Public Administration.

New England Radiological Health Committee, Radon's Impact on State Radiation Control Programs. October 28–29, 1986.

U.S. Department of Health and Human Resources, Medical X-Ray Protection, March 23–27, 1987.

U.S. Department of Health and Human Resources, Basic Course for Investigators: Diagnostic X-Ray. April 27 to May 7, 1987.

Federal Emergency Management Agency, Radiological Emergency Response Course. September 9–18, 1987.

U.S. Nuclear Regulatory Commission, Inspection Procedures Course. September 25–29, 1989.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 18–22, 1991.

Jay Carl Hyland—B.S., Engineering Physics, University of Maine, Orono.

Maine Emergency Management Agency, Fundamentals Course for Radiological Monitors. November 30 to December 1, 1988.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 27–31, 1989.

Federal Emergency Management Agency, Radiological Accident Assessment. May 22–26, 1989.

U.S. Nuclear Regulatory Commission, Inspection Procedures Course. June 19–23, 1989.

U.S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. July 10 to August 11, 1989.

U.S. Nuclear Regulatory Commission, Nuclear Transportation. August 14–18, 1989.

Federal Emergency Management Agency, Radiological Emergency Response Course. August 23 to September 1, 1989.

U.S. Nuclear Regulatory Commission, Special Topics Workshop. November 27 to December 1, 1989.

U.S. Nuclear Regulatory Commission, Licensing Practices and Procedures. June 11–15, 1990.

U.S. Nuclear Regulatory Commission, Special Topics Workshop. August 27–29, 1990.

U.S. Nuclear Regulatory Commission, Safety Aspects of Industrial Radiography. September 24–28, 1990.

Cheryl Baker—B.S., Chemistry University of Maine, Orono. U.S. Nuclear Regulatory Commission,

Radiochemistry. February 9–13, 1981.
Public Health Laboratory, Radiation Safety in the Laboratory. July 28, 1983.
Federal Emergency Management Agency, Radiological Accident Assessment. March 5–9, 1984.
New England Radiological Health Committee, Radiological Laboratory Workshop. April 24–25, 1984.
Oak Ridge Associated Universities, Health Physics and Radiation Protection. July 9 to August 10, 1984.
New England Radiological Health Committee, Radiation Therapy Inspections. October 23–25, 1984.
New England Radiological Health Committee, Radiological Laboratory Workshop. April 30 to May 2, 1985.
New England Radiological Health Committee, Non Ionizing Radiation. October 29–30, 1985.
New England Radiological Health Committee, Radon's Impact on State Programs. October 28–29, 1986.
New England Radiological Health Committee, Radiological Laboratory Workshop. May 5–7, 1987.

Reference: Maine Program Statement.

21. *Conditions Applicable to Special Nuclear Material, Source Material and Tritium.* Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms (1) transfers of special nuclear material, source material and tritium and (2) periodic inventory data.

The State's regulations do not prohibit or interfere with the duties imposed by the NRC on holders of special nuclear material owned by the U.S. Department of Energy or licensed by NRC, such as the responsibility of licensees to supply to the NRC reports of transfer and inventory.

Reference: State of Maine Rules Relating to Radiation Protection Section A.1.

22. *Special Nuclear Material Defined.* Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U^{-235} in quantities not exceeding 350 grams of contained U^{-235}; uranium 233 in quantities no exceeding 200 grams: Plutonium in quanties not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$\frac{175 \text{ (grams contained U–235)}}{350} + \frac{50 \text{ (grams U–233)}}{200} + \frac{50 \text{ (grams Pu)}}{2200}$$

(This definition is subject to change by future Commission rule or regulation.)

The definition of special nuclear material in quantities not sufficient to form a critical mass, as contained in the Maine regulations, is uniform with the definition in 10 CFR Part 150.

Reference: State of Maine Rules Relating to Radiation Protection Section A.2.A(62), Definition of Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

Administration

23. *Fair and Impartial Administration.* State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:

(a) Formulation of rules of general applicability;

(b) Approving or denying applications for licenses or authorization to possess and use radioactive materials, and

(c) Taking disciplinary actions against licensees.

The Maine statute and regulations provide for administrative and judicial review of actions taken by the Division of Health Engineering which includes the Maine Radiation Control Program.

Reference: Maine Administrative Procedure Act, State of Maine Rules Relating to Radiation Protection Sections A.9, A.11, C.22, and J.

24. *State Agency Designation.* The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.

The Maine Department of Human Services in which the Maine Radiation Control Program is located has been designated as the State's radiation control agency.

References: Maine Radiation Protection Act, section 674.1 and 686.

25. *Existing NRC Licenses and Pending Applications.* In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or the processing of license applications, by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.

Maine regulations have provisions for NRC licensees to possess a like license issued under the Maine regulations and the Maine Act. These licenses will expire either 90 days after receipt from the Agency of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is earlier.

Reference: State of Maine Rules Relating to Radiation Protection Section C.19.

26. *Relations With Federal Government and Other States.* There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.

The proposed agreement declares that the State will use its best efforts to cooperate with the NRC and the other

Agreement States in the formulation of standards and regulatory programs for the protection against the hazards of radiation and to assure that the State's program will continue to be compatible with the Commission's program for the regulation of like materials.

Reference: Proposed Agreement between the State of Maine and the Nuclear Regulatory Commission, Article VI.

27. *Coverage, Amendments, Reciprocity.* The proposed Maine agreement provides for the assumption of regulatory authority over the following categories of materials within the State:

(a) Byproduct material, as defined by Section 11e.(1) of the Atomic Energy Act, as amended.

(c) Source materials.

(c) Special nuclear materials in quantities not sufficient to form a critical mass.

Reference: Proposed Agreement, Article I.

Provision has been made by Maine for the reciprocal recognition of licenses to permit activities within Maine of persons licensed by other jurisdictions. This reciprocity is like that granted under 10 CFR part 150.

Reference: State of Maine Rules Relating to Radiation Protection Section 3.X.

28. *NRC and Department of Energy Contractors.* The State's regulations provide that certain NRC and DOE contractors or subcontractors are exempt from the State's requirements for licensing and registration of sources of radiation which such persons receive, possess, use, transfer, or acquire.

Reference: State of Maine Rules Relating to Radiation Protection Section A.3.B.

III. Staff Conclusion

Section 274d of the Atomic Energy Act of 1954, as amended, states:

The Commission shall enter into an agreement under subsection b of this section with any State if:

(1) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and

(2) The Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed amendment.

The staff has concluded that the State of Maine meets the requirements of section 274 of the Act. The State's statutes, regulations, personnel, licensing, inspection and administrative procedures are compatible with those of the Commission and adequate to protect the public health and safety with respect to the materials covered by the proposed agreement. Since the State is not seeking authority over uranium milling activities, subsection o. is not applicable to the proposed Maine agreement.

Dated at Rockville, Maryland, this 22nd Day of November 1991.

Carlton Kammerer,

Director, Office of State Programs.

Appendix A—Agreement Between the United States Nuclear Regulatory Commission and the State of Maine for Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended

Whereas, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and section 161 of the Act with respect to byproduct materials as defined in sections 11e. (1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

Whereas, The Governor of the State of Maine is authorized under Maine Revised Statutes Annotated section 284 to enter into this Agreement with the Commission; and,

Whereas, The Governor of the State of Maine certified on March 5, 1990, that the State of Maine (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

Whereas, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemptions from licensing of those materials subject to this Agreement; and

Whereas, This Agreement is entered into pursuant to the provisions of the Act, as amended;

Now Therefore, It is hereby agreed between the Commission and the Governor of the State, acting in behalf of the State, as follows:

Article I

Subject to the exceptions provided in articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under chapters 6, 7, and 8, and section 161 of the Act with respect to the following materials:

A. Byproduct materials as defined in section 11e.(1) of the Act;

B. Source materials; and

C. Special nuclear materials in quantities not sufficient to form a critical mass.

Article II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission;

E. The land disposal of source, byproduct and special nuclear material received from other persons; and,

F. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

Article III

This Agreement may be amended, upon application by the State and

approval by the Commission, to include the additional area(s) specified in article II, paragraph E or F, whereby the State can exert regulatory control over the materials stated herein.

Article IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article V

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

Article VI

The Commission will use its best efforts to cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

Article VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any Agreement State. Accordingly, the Commission and the State agree to use their best efforts to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of section 274 of the Act. The Commission may also, pursuant to section 274j of the Act, temporarily suspend all or part of this Agreement if, in the judgement of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with section 274 of the Act.

Article IX

This Agreement shall become effective on _____, and shall remain in effect unless and until such time as it is terminated pursuant to article VIII.

Done at Augusta, Maine, in triplicate, this _____, 1991.

For the U.S. Nuclear Regulatory Commission.

Ivan Selin,

Chairman.

For the State of Maine

John R. McKernan, Jr.,

Governor.

[FR Doc. 91-30060 Filed 12-16-91; 8:45 am]

BILLING CODE 7590-01-M

POSTAL SERVICE

Privacy Act; Notice of a Computer Matching Program

AGENCY: United States Postal Service.

ACTION: Notice of a computer matching program between the United States Postal Service and the Small Business Administration.

SUMMARY: Subsection (e)(12) of the Privacy Act, as amended by The Computer Matching and Privacy Protection Act of 1988 (Public Law 100-503) requires agencies to publish advance notice of new matching programs. This publishes notice that the United States Postal Service (USPS) proposes to conduct a computer matching program with the Small Business Administration (SBA). The program will compare USPS payroll and SBA debtor records to identify postal employees delinquently indebted to the federal government under certain programs administered by SBA and to collect those debts under the salary offset provisions of the Debt Collection Act of 1982 when voluntary payment is not made.

DATES: Comments must be received no later than January 16, 1992. Unless comments are received that result in a contrary determination, the matching program will begin no sooner than 30 days after this published notice has been sent to Congress and the Office of Management and Budget and a copy of the matching agreement has been sent to Congress.

ADDRESSES: Comments may be mailed to the RECORDS OFFICER, US POSTAL SERVICE, 475 L'ENFANT PLAZA SW, WASHINGTON, DC 20260-5010, or delivered to Room 8141 at the above address between 8:15 a.m. and 4:45 p.m. Comments received may also be inspected during the above hours in Room 8141.

FOR FURTHER INFORMATION CONTACT: Betty Sheriff, Records Office (202) 268-5158.

SUPPLEMENTARY INFORMATION: Set forth below is a description of the matching program proposed by this notice. The description complies with Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818), and OMB Bulletin 89-22, "Instructions on Reporting Computer Matching Programs to the Office of Management and Budget (OMB), Congress and the Public."

Report of Computer Matching Program—United States Postal Service and Small Business Administration (Comparing USPS Payroll and SBA Debtor Records)

A. Participating Agencies. The United States Postal Service (USPS) is the recipient agency and will perform the computer match with debtor records provided by the Small Business Administration (SBA), the source agency in this matching program.

B. Purpose of the Matching Program. This matching program will compare USPS payroll and SBA delinquent debtor files for the purposes of identifying postal employees who may owe delinquent debts to the federal

government under certain programs administered by SBA. The pay of an employee identified and verified as a delinquent debtor may be offset under the provisions of the Debt Collection Act of 1982 when voluntary payment is not made.

C. Legal Authorities Authorizing Operation of the Match. This matching program will be undertaken under the authority of the Debt Collection Act of 1982 (Public Law 97–365) which authorizes federal agencies to offset a federal employee's salary as a means of satisfying delinquent debts owed to the United States.

D. Categories of Individuals Matched and Identification of Records Used. The systems of records maintained by the participant agencies under the Privacy Act of 1974, as amended, from which records will be disclosed for the purpose of this matching program are:

1. USPS will use records from its system "Finance Records—Payroll System, USPS 050.020" containing records about approximately 850,000 employees. Disclosure will be made pursuant to routine use No. 24 of USPS 050.020 which last appeared at 54 FR 43867, dated October 26, 1989, amended at 55 FR 20554, dated May 17, 1990 and 56 FR 13505, dated April 2, 1991.

2. SBA will use records from its "Loan Case File, SBA 075" containing approximately 100,000 debtor records, of which approximately 10,000 debtor records, of which approximately 10,000 pertain to delinquent loans.

E. Description of the Matching Program. The SBA will provide to USPS a magnetic computer tape containing the names, social security numbers (SSN), home address and work location of its loan defaulters. By computer, the USPS will compare that information with its payroll file, establishing matched individuals (i.e. "hits") on the basis of like SSNs. For each matched individual, the USPS will provide to SBA the name, SSN, home address and work location. SBA will screen that data to verify that the matched individual is in fact a delinquent debtor not in a repay status. The identity and debtor status of an individual will be verified by SBA through a review of its manual application and payment files and independent inquiries as needed.

The Debt Collection Act requires SBA to provide the suspected debtor with certain due process rights including 30 days advance notice and an opportunity to contest the alleged debt. Only after SBA has afforded the debtor these opportunities and certified over the signature of an authorized agency official that all due process procedures have been followed will involuntary offset be made.

F. Beginning and Ending Dates of the Matching Program. The matching program is expected to begin in November 1991 and to continue in effect for a period not to exceed 18 months. The agreement may be extended for one additional year beyond that period if, within 90 days prior to the actual expiration date, the Data Integrity Boards of the USPS and SBA find that the program will be conducted without change and each party certifies that the program has been conducted in compliance with the Matching Agreement.

Stanley F. Mires,

Assistant General Counsel, Legislative Division.

[FR Doc. 91–30000 Filed 12–16–91; 8:45 am]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–30057; File No. SR–CBOE–91–38]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to the Administration of the Floor Member Qualification Examination

December 10, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 12, 1991, the Chicago Board Options Exchange, Inc. ("CBOE") or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE is filing this proposed rule change pursuant to a Commission request that all qualification examinations administered by the Exchange be filed with the Commission. Accordingly, the CBOE has submitted its Floor Member Qualification Examination ("Exam") for Commission review and approval. The Exchange states that the Exam is designed specifically to test applicants' knowledge in a variety of areas, including general trading principles and procedures as well as CBOE rules and policies.

The text of the proposed rule is available at the Office of the Secretary, CBOE, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and statutory basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The Commission requires that all self-regulatory organizations file for review and approval all practices imposing qualification standards.[2] In a letter dated April 8, 1991, the Commission specifically requested that the CBOE submit as proposed rule changes all qualification examinations administered by the Exchange. Accordingly, the CBOE is submitting the contents of its qualification examination and related materials as a proposed rule change in response to this Commission request.

The CBOE administers only one qualification examination, the Floor Member Qualification Examination.[3] Pursuant to CBOE Rule 3.9(c)(2), all applicants for CBOE membership who are "seeking trading privileges" are required to take the Exam, which includes individual members and the nominees of member organizations.[4] The same examination is given regardless of whether the applicant is seeking to act in the capacity of a floor broker or a market-maker. Moreover, in addition to new membership applicants and nominees, if a member has been off a seat or on inactive nominee status for

[1] On November 25, 1991, the CBOE amended the filing to provide that it was submitted pursuant to section 19(b)(2) of the Act instead of section 19(b)(3)(A) of the Act, allowing for notice and comment rather than summary effectiveness.

[2] *See* Securities Exchange Act Release No. 17258 (October 30, 1980), 45 FR 73906.

[3] *See* CBOE Rule 3.9(c)(2).

[4] *See* CBOE Rules 6.71 and 8.2.

more than one year, the Exchange requires such person to retake the Exam.

The Exam is administered by the Options Institute, which is the educational arm of the Exchange, and offered approximately one time per month. Each test consists of 100 questions, with a score of 75% or better required to pass. According to CBOE Rule 3.4(b), membership will be denied by the Membership Committee where the applicant has failed the Exam. The applicant must then wait 30 days before retaking the Exam if he or she fails it once, 60 days if a second attempt is failed, and 120 days if a third or subsequent attempt is failed.[5]

The CBOE states that the Exam was specifically designed for CBOE membership applicants in order to test the applicants' knowledge in a variety of areas, including general trading principles and procedures as well as specific CBOE rules and policies.

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act, and furthers the objectives of section 6(b)(5), 6(c)(3)(A) and 7(c)(3)(B), in particular. The Exchange further states that the proposed rule change is designed to examine the training, experience, and competence of applicants for CBOE membership and verify such applicants' qualifications for Exchange membership. In addition, the CBOE believes that the proposed rule change serves to protect investors and the public interest by helping to assure member competence.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by January 7, 1992.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-30063 Filed 12-16-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-30048; File Nos. SR-PSE-91-33]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc., Relating to Options on Preferred Stock and American Depository Receipts

December 9, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that the Pacific Stock Exchange, Inc. ("PSE"), on November 20, 1991, filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PSE requests approval to list options on preferred stocks and American Depository Receipts ("ADRs") that meet established uniform options listing standards and guidelines.[1] Specifically, the Exchange proposes to amend its uniform options listing standards rules to provide that, if a preferred stock or an ADR meets the Exchange's current initial listing standards criteria, then the preferred stock or the ADR is appropriate for options trading.

The text of the proposed rule change is available at the Office of the Secretary, PSE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The Exchange is filing its proposal to establish its policy that, like common stock, securities other than common stock will be required to meet the standards and guidelines set forth in the Exchange's uniform options listing standards rules, in order to be approved for listing and trading on the Exchange.[2] To that end, the Exchange is proposing that its options listing standards rules be amended to include preferred stock or ADRs as a security which is appropriate for options trading.

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[5] *See* CBOE Rule 3.4(b).

[1] *See* PSE Rule 3.6.

[2] On August 29, 1991, the Commission approved uniform proposals by the options exchanges to lower the options listing standards. *See* Securities Exchange Act Release No. 29628 (August 29, 1991), 56 FR 43949 ("Options Listing Standards Approval Order"). In footnote eleven of that approval order, the Commission stated that the "Exchanges must file separate rule changes pursuant to section 19(b) of the Act for options on securities other than common stock."

The Exchange believes the proposed rule change is consistent with section 6(b) of the Act, in general, and section 6(b)(5) in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by January 7, 1992.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[3]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-30065 Filed 12-16-91; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-18434; File No. 812-7747]

MB Variable Life Insurance Company, et al.

December 10, 1991.

AGENCY: Securities and Exchange Commission (the "SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: MB Variable Life Insurance Company ("MB Variable"), Separate Account B of MB Variable Life Insurance Company (the "Account"), and Directed Services, Inc. ("DSI").

RELEVANT 1940 ACT SECTIONS: Exemptions requested pursuant to section 6(c) from sections 2(a)(35), 26(a)(2)(C) and 27(c)(2) of the 1940 Act.

SUMMARY OF THE APPLICATION: Applicants seek an order to permit the deduction of mortality and expense risk charges from the assets of the Account under a deferred variable annuity contract and an immediate variable annuity contract, and to permit the deduction of a premium-based sales load from the accumulation value of the Account.

FILING DATES: The application was filed on July 1, 1991.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the requested exemption will be granted. Any interested person may request a hearing on this application or ask to be notified if a hearing is ordered. Any requests must be received by the Commission by 5:30 p.m., on January 6, 1992. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the Commission, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Applicants, c/o MB Variable Life Insurance Company, 909 Third Avenue, 19th Floor, New York, New York 10022.

FOR FURTHER INFORMATION CONTACT: Michael V. Wible, Senior Attorney, at (202) 272-2026, or Heidi Stam, Assistant Chief, Office of Insurance Products (Division of Investment Management), at (202) 272-2060.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the Commission's Public Reference Branch.

Applicant's Representations

1. MB Variable is a stock life insurance company organized under the laws of Minnesota on January 2, 1973. From January 2, 1973 through December 31, 1987, the name of the company was St. Paul Life Insurance Company. On December 31, 1987, the company was renamed Golden American Life Insurance Company ("Golden American"). On March 7, 1988, all of the stock of Golden American was acquired by The Golden Financial Group, Inc., a financial services holding company. On October 19, 1990, The Golden Financial Group, Inc. merged with and into MBL Variable, Inc., a wholly-owned direct subsidiary of The Mutual Benefit Life Insurance Company ("Mutual Benefit"). On January 1, 1991, MBL Variable, Inc. became a wholly-owned indirect subsidiary of Mutual Benefit and Golden American became a wholly-owned direct subsidiary of Mutual Benefit. Golden American's name has been changed to MB Variable in the state of Minnesota and is in the process of being changed in other jurisdictions.

2. The Account is a distinct separate investment account of MB Variable which acts as a funding vehicle for a deferred variable annuity ("Deferred Annuity") and an immediate variable annuity certain ("Annuity Certain") (the Deferred Annuity and Annuity Certain are collectively referred to as the "Contracts"). DSI serves as the principal underwriter for and distributor of the Contracts.

3. The Deferred Annuity is a flexible premium payment contract which provides for an initial premium payment and allows for subsequent premium payments, if desired. The Contract owner is under no obligation to make additional payments.

[3] 17 CFR 200.30-3(a)(12) (1990).

4. The Annuity Certain is an immediate annuity which provides for a single premium payment by the Contract owner and variable annuity payments over a fixed period of time.

5. The sales loads imposed under the Contracts may be structured in two ways. Under Contracts currently being offered, deferred loading at a maximum rate of 7.50% of each payment is deducted from each premium payment. If the payment received at issue on one Contract or several simultaneously purchased Contracts exceeds specified limits, the Applicants may reduce this load. This charge is allocated to cover distribution charges. All deferred loading applicable to initial or additional premium payments is deducted by MB Variable at the time of payment but is advanced back to the investment divisions of the Account and is recovered periodically by MB Variable from the divisions in equal installments over a time period specified in the Contracts. If the Contract owner surrenders a Contract, any remaining deferred loading will be recovered by MB Variable a that time. A portion of the deferred loading will be recovered by MB Variable in connection with partial withdrawals in excess of 15% of accumulation value. For purposes of the provisions of the 1940 Act applicable to sales load, the deferred loading is a front-end sales load. The Applicants are not relying on rule 6c–8 in connection with this charge.

6. In the future, MB Variable may offer contracts with the combination of a premium-based sales load and a contingent deferred sales load in lieu of the deferred sales load described above. These charges are allocated to cover distribution expenses. MB Variable will deduct the premium-based sales load from the accumulation value in an amount equal to a maximum of 7.50% of each premium payment. The premium-based charge will be deducted in equal installments for a period of not more than ten years or until such time as the Contract owner surrenders the Contract or annuitizes.

7. A contingent deferred sales load may also be deducted. If a Contract owner surrenders a Contract during the first ten years after a premium has been paid, the maximum contingent deferred sales load will be 7.50% of such premium in year one and will decline to zero after year ten. A contingent deferred sales load may also be deducted for partial withdrawals in excess of 15% of the accumulation value. MB Variable will monitor sales load on the individual Contract owner basis to ensure that the sum of the premium-based sales load and any contingent deferred sales load will not exceed 9.00% of each premium payment. Once a Contract is purchased, the sales load will not increase. Applicants are relying on Rule 6c–8 to deduct the contingent deferred sales load.

8. In a Deferred Annuity, an annual administrative charge of $40 is deducted in equal installments on each Contract processing date from the accumulation value of a Contract to reimburse MB Variable for the anticipated actual cost of administrative expenses relating to the Contract. There may also be an asset-based administrative charge accrued daily, not to exceed on an annual basis 0.10% of the assets of each Contract. In certain versions of the Contract which do not have an asset-based administrative charge, the per policy administrative charge may be charged by MB Variable. However, the charge is guaranteed not to exceed $60 annually. The administrative charge assessed under the Contract remains in effect for the life of the Contract.

9. In certain versions of the Annuity Certain, an administrative charge of 0.25% is applied to single premiums of less than a specified minimum in the same manner and over the same time period as the deferred load. The specified minimum is determined taking into account administrative cost savings based on volume. The administrative charge is to cover MB Variable's ongoing administrative expenses and will not exceed the cost of services to be provided over the life of the Contract. There may also be an asset-based administrative charge accrued daily, not to exceed 0.10% annually of the assets of each Contract.

10. The Applicants submit that the imposition of a sales charge in the form of a premium-based charge to be deducted from accumulation value is more favorable to a Contract owner than the deduction of sales charge from premiums paid; the conventional way of imposing such charges. The amount of the Contract owner's investment in the Account is not reduced as it would be if these charges were taken in full directly from premiums paid. Moreover, the total amount charged to any Contract owner is no greater than it would be if these charges were taken from premiums paid. Finally, the fact that the entire amount of the charge has not been deducted will favorably affect the amount of the death benefit. As a result, the Applicants submit that Contract owners will obtain the advantages described above, which arise from the deferred nature of the charge, without incurring any additional cost.

11. Accordingly, the Applicants request exemption from sections 2(a)(35), 26(a)(2)(C) and 27(c)(2) of the 1940 Act to the extent necessary to permit the premium-based sales load to be deducted from accumulation value in the manner described above.

12. In the Deferred Annuity, MB Variable guarantees a death benefit payable to the beneficiary if the Contract owner or Annuitant dies prior to the annuity commencement date. MB Variable imposed a charge for the guaranteed death benefit under old Contracts and may in the future offer Contracts for which it will impose a charge. This charge is not an asset-based charge. Rather, it is an account charge imposed to compensate MB Variable for the risk that the guaranteed death benefit due under a Deferred Annuity when the annuitant dies during the accumulation phase may exceed the normal death benefit otherwise payable. In the Deferred Annuity, the guaranteed death benefit charge would be at a maximum rate of $1.20 per $1,000.00 of guaranteed death benefit per year. To the extent that a guaranteed death benefit charge is imposed with respect to a particular Deferred Annuity Contract, the mortality and expense risk charge will be limited to a level such that the sum of the mortality and expense risk charge and an asset-based approximation of the guaranteed death benefit charge does not exceed 1.25% of the assets in a division of the Account. The Applicants have previously received the exemptive relief necessary to deduct this charge for the guaranteed death benefit.

13. With respect to Contracts issued on a prospective basis, the daily mortality and expense risk charge will be at the maximum rate of 0.003446% (equivalent to an annual rate of 1.25%) of the assets in each division of the Account. In the Deferred Annuity, approximately 0.75% is allocated to the mortality risk and 0.50% is allocated to the expense risk. In the Annuity Certain, approximately 0.625% is allocated to the mortality risk and 0.625% is allocated to the expense risk. The mortality and expense risk charge is paid daily to MB Variable to compensate for the mortality and expense risk MB Variable assumes under the Contract. The Applicants request an exemption from sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to the extent necessary to deduct the mortality and expense risk charge under the Contracts.

14. The mortality risk assumed by MB Variable arises from its obligations to continue to make annuity payments under the Contracts determined in

accordance with the guaranteed annuity tables and other provisions of the Contracts, regardless of how long each annuitant lives and regardless of how long all payees as a group live. The mortality risk under the Deferred Annuity is the risk that, after annuitization or upon selection of an annuity option with a life contingency, annuitants will possibly live longer than indicated by MB Variable's actuarial projections, resulting in higher than expected payments during the payout phase, since the payment options are guaranteed to be not less than the tables discussed in the Deferred Annuity. In the Deferred Annuity, MB Variable also assumes a risk to pay out a guaranteed death benefit if the death benefit is in excess of the accumulation value.

15. In the Annuity Certain, the mortality risk assumed by MB Variable relates to the fact that, at all times, MB Variable will offer the option to convert the Annuity Certain, which does not provide for payments based on life contingencies, to one or more annuity contracts that provide for payments based on life contingencies. The mortality risk assumed by MB Variable is the risk that annuitants, or beneficiaries after the death of the annuitant, will choose one such option and will possibly live longer than MB Variable's actuarial projections indicate, resulting in higher than expected payments during the payment phase, since any payment option is guaranteed to be not less than the tables discussed in the Annuity Certain.

16. In addition, MB Variable assumes a risk that the charges for the administrative expenses may not be adequate to cover such expenses.

17. If the charges under the Contracts are insufficient to cover the actual cost of the mortality and expense risk, the loss will fall on MB Variable; conversely, if the deduction proves more than sufficient, the excess will be profit to MB Variable. Any profits resulting to MB Variable from the mortality and expense risk charge can be used by MB Variable, at its discretion, for any business purposes, including distribution expenses relating to the Contracts.

18. With respect to the level of mortality and expense risk charge, the Applicants represent that they have reviewed publicly available information regarding the aggregate level of the mortality and expense risk charge under comparable variable annuity contracts currently being offered in the insurance industry taking into consideration such factors as current charge levels, the manner in which charges are imposed, the presence of charge level or annuity rate guarantees and the markets in which the Contracts will be offered. Based upon the foregoing, the Applicants represent that the mortality and expense risk charge under the Contracts is within the range of industry practice for comparable contracts. The Applicants will maintain and make available to the Commission, upon request, a memorandum outlining the methodology underlying this representation.

19. The Applicants do not believe that the deferred load imposed under the Contracts will necessarily cover the expected costs of distributing the Contracts. Any "shortfall" will be made up from the general account assets which will include amounts derived from the risk charges. MB Variable has concluded that there is a reasonable likelihood that the distribution financing arrangement used in connection with the Contracts will benefit the Account and the Contract owners. MB Variable will keep and make available to the Commission, upon request, a memorandum setting forth the basis for this representation.

20. The Applicants represent that the Account will only invest in underlying funds which have undertaken to have a board of directors/trustees, a majority of whom are not interested persons of any such fund, formulate and approve any plan under rule 12b-1 under the 1940 Act to finance distribution expenses.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-30064 Filed 12-16-91; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2539]

Territory of Guam; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 4, 1991, I find that the Territory of Guam constitutes a disaster area as a result of damages caused by Typhoon Yuri which occurred November 27-28, 1991. Applications for loans for physical damage may be filed until the close of business on February 3, 1992, and for loans for economic injury until the close of business on September 4, 1992, at the address listed below:

Disaster Area 4 Office, Small Business Administration, P.O. Box 13795, Sacramento, CA 95853-4795

or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	8.500
For Economic Injury	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 253906 and for economic injury the number is 749100.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 5, 1991.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 91-30083 Filed 12-16-91; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2532; Amdt. #2]

Maine; Declaration of Disaster Loan Area

The above-numbered Declaration is hereby amended in accordance with an amendment dated November 27, to the President's major disaster declaration of November 7, to include Knox, Lincoln, and Sagadahoc Counties in the State of Maine as a disaster area as a result of damages caused by a major coastal storm beginning on October 30 and continuing through November 2, 1991.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Hancock, Kennebec and Waldo in the State of Maine may be filed until the specified date at the previously designated location.

Any county contiguous to the above-named primary county and not listed herein has previously been named as contiguous or primary counties for the same occurrence.

All other information remains the same, i.e., the termination date for filing applications for physical damage is January 6, 1992, and for economic injury until the close of business on August 7, 1992.

The economic injury number assigned to this disaster for the State of Maine is 746100.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 9, 1991.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 91-30084 Filed 12-16-91; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements filed during the Week Ended December 6, 1991

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: 47873.
Date filed: December 3, 1991.
Parties: Members of the International Air Transport Association.
Subject: Reso 024F/033F—Tariff Changes From Madagascar.
Proposed Effective Date: Upon Necessary Government Approvals.

Docket Number: 47874.
Date filed: December 3, 1991.
Parties: Members of the International Air Transport Association.
Subject: Mail Vote 524—Fares/charges from Turkey.
Proposed Effective Date: January 1, 1992.

Docket Number: 47875.
Date filed: December 3, 1991.
Parties: Members of the International Air Transport Association.
Subject: COMP Meet/C 0157 dated November 13, 1991, Minutes & Report—5th Joint Cargo Rates Board.
Proposed Effective Date: December 1, 1991.

Docket Number: 47876.
Date filed: December 3, 1991.
Parties: Members of the International Air Transport Association.
Subject: TC23 Reso/P 0475 dated November 20, 1991, Expedited Middle East-TC3 Resos R-1 to R-3, TC23 Reso/P 0478 dated November 21, 1991, Expedited Africa-TC3 Resos R-4 to R-7, TC23 Reso/P 0482 dated November 22, 1991, Expedited Europe-Southwest Pacific Resos R-8.
Proposed Effective Date: January 1, 1992.

Docket Number: 47877.
Date filed: December 3, 1991.
Parties: Members of the International Air Transport Association.
Subject: SNATC/2059 dated October 24, 1991, US-Europe Agreement R-1 to R-16, SNATC/2060 dated October 24, 1991, US-Europe Agreement R-17, SNATC/2064 dated November 27, 1991, Fares Tables.
Proposed Effective Date: January 1, 1992.

Docket Number: 47886.
Date filed: December 4, 1991.
Parties: Members of the International Air Transport Association.
Subject: TC23 Reso/P 0483 dated November 22, 1991, Expedited Europe-Southwest Paciic R-1 to R-4.
Proposed Effective Date: March 1, 1992.

Docket Number: 47887.
Dated filed: December 4, 1991.
Parties: Members of the International Air Transport Association.
Subject: Telex dated November 18, 1991, Mail Vote 523 (Fares from Swtizerland).
Proposed Effective Date: January 1, 1992.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 91-30026 Filed 12-16-91; 8:45 am]

BILLING CODE 4910-62-M

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended December 6, 1991

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: 47883.
Date filed: December 4, 1991.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 11, 1991.
Description: Application of American Airlines, Inc., pursuant to section 401 of the Act and Subpart Q of the Regulations, applies for a certificate of public convenience and necessity to engage in foreign air transportation of persons, property, and mail between Los Angeles, California, and Nagoya, Japan.

Docket Number: 47896.
Date filed: December 6, 1991.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 3, 1992.
Description: Application of Trans World Airlines, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations applies for renewal of the authority set forth in its certificate of public convenience and necessity for Route 523, namely to engage in foreign air transportation of persons, property and mail between Baltimore, Maryland and London, United Kingdom.

Docket Number: 47900.
Date filed: December 6, 1991.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 3, 1992.
Description: Application of Delta Air Lines, Inc., pursuant to section 401 of the Act and subpart Q of the regulations applies to renew its certificate of public convenience and necessity to permit Delta to continue to provide scheduled air transportation of persons, property and mail between Cincinnati, Ohio and London (Gatwick), England.

Docket Number: 47901.
Date filed: December 6, 1991.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 3, 1992.
Description: Application of Lauda Air Luftfahrt AG, pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a foreign air carrier permit authorizing it to engage in scheduled foreign air transportation of persons, property and mail between a point or points in Austria and points in the United States.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 91-30025 Filed 12-16-91; 8:45 am]

BILLING CODE 4910-62-M

National Highway Traffic Safety Administration

[Docket No. 91-60; Notice 1]

Solectria Corporation; Receipt of Petition for Temporary Exemption From Seven Federal Motor Vehicle Safety Standards

Solectria Corporation of Arlington, Massachusetts, has applied for a temporary exemption from seven Federal motor vehicle safety standards for passenger cars that it converts to electric power. The basis of the petition is that compliance with the standards would cause substantial economic hardship.

Notice of receipt of the petition is published in accordance with agency regulations on the subject (49 CFR part 555), and does not represent any judgment of the agency on the merits of the petition.

Petitioner intends to convert new Geo Metro passenger cars to electric power. The vehicles, seating 2, 4, and 5 passengers, would be marketed as the Solectria Force. The vehicles to be converted have been certified by their original manufacturer to conform to all applicable Federal motor vehicle safety standards. However, petitioner has determined that the vehicles may not conform with all or part of seven Federal motor vehicle safety standards after their modification. The standards for which exemptions are requested are discussed below.

1. Standard No. 103, Windshield Defrosting and Defogging Systems.

Petitioner states that the Force relies on an electric resistance/forced hot air heater to provide cabin heat and defrosting. While it believes that the heating system will perform similarly to the original one, recertification will be required. It requests an exemption of one year for testing for compliance, and such subsequent modifications as may be required to certify compliance with the standard.

2. Standard No. 204, Steering Control Rearward Displacement.

3. Standard No. 208, Occupant Crash Protection.

4. Standard No. 212, Windshield Mounting.

5. Standard No. 219, Windshield Zone Intrusion.

Exemption is requested from these four standards for a period of two years. The conversion of the vehicle to electric power results in a net weight increase of 250 pounds for the 4- and 5-passenger models, which is 15% over the weight at which the vehicle was originally certified, and of 350 pounds for the 2-passenger model, which is 20% over original certification weight. Petitioner states that "thirty-mile per hour barrier crash testing is needed to determine the actual energy absorbing characteristics of the three Force configurations."

6. Standard No. 214, Side Door Strength.

7. Standard No. 216, Roof Crush Resistance.

These standards require vehicle components to be able to withstand a crush force determined by the vehicle curb weight. As noted above, the Force's curb weight, is 15% and 20%, depending on the model, over the weight of the vehicle originally certified to meet these standards. The petitioner requests an exemption of two years after which it expects to be able to certify compliance with these standards.

Petitioner argues that to require immediate compliance would create substantial economic hardship. As of September 30, 1990, the end of its first fiscal year, the company had a net income of $8,185.66. At the end of the first ten months of fiscal 1991, it had an additional net income of $7,360.26. Aside from testing for compliance with Standard No. 103, the cost for "one set" of testing for compliance with Standard No. 103, the cost for "one set" of testing for the remaining standards on one vehicle is approximately $30,000, exclusive of the costs of delivering the vehicle to the test facility. Because the Force will be available in three configurations, the petitioner believes that it must test all configurations for compliance. It estimates a total testing cost of $216,100. An exemption would permit vehicle sales and the generation of cash permitting testing while the exemptions are in effect. It plans to produce ten vehicles in its first year of production, with an additional 50 vehicles in the second year. A denial of the petition would delay its production while it attempted to test for conformance, but the costs of testing immediately would require a retail price of $50,000 for a Force. Petitioner doubts that it could sell a car at this price, and that, accordingly, it would be forced out of business in the year following a denial of its petition.

According to the petitioner, granting the exemption would be in the public interest and consistent with the National Traffic and Motor Vehicle Safety Act by helping to relieve environmental problems associated with automotive transportation. It believes that "the Force can make a very positive contribution to the country's clean transportation needs quickly and effectively."

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: January 16, 1992.

(15 U.S.C. 1410; delegations of authority at 49 CFR 1.50, and 501.8)

Issued on December 11, 1991.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 91-30022 Filed 12-16-91; 8:45 am]

BILLING CODE 4910-59-M

[Docket No. 91-45; Notice 2]

Thomas Built Buses, Inc.; Grant of Petition for Determination of Inconsequential Noncompliance

This notice grants the petition by Thomas Built Buses, Inc. (Thomas Built), of High Point, North Carolina, to be exempted from the notification and remedy requirements of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) for an apparent noncompliance with 49 CFR 571.205, Federal Motor Vehicle Safety Standard No. 205, "Glazing Materials." The basis of the petition is that the noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published on September 19, 1991, and an opportunity afforded for comment (56 FR 47519).

Paragraph S6.2 of Standard No. 205 specifies that a number designating the material used and the symbol "DOT" shall be marked on all glazing materials by prime glazing material manufacturers.

Between February 1980 and April 1991, Thomas Built produced 2,763 buses and school buses, both over and under 10,000 pounds GVWR (for 16 to 72 passengers) which did not comply with the above mentioned requirements of Standard No. 205. The material designation and the symbol "DOT" were not marked on the wire reinforced glass installed in the lower portion of the rear emergency door. Thomas Built supported its petition with the following:

Although the glass did not have the DOT mark it meets all of the requirements of Standard No. 205 and ANSI Z26.1 A test report (#506406) from an independent testing facility was included with the petition.

Finally, the wire reinforced glass was installed only in the lower portion of the rear emergency door. This is permissible under both Standard No. 205 and ANSI Z26.1.

No comments were received on the petition.

Standard No. 205 is one of several motor vehicle equipment safety standards which requires that the DOT symbol be affixed to the item as the certification of compliance required by section 114 of the National Traffic and Motor Vehicle Safety Act. NHTSA has regarded previous instances of omission of the DOT symbol as a failure to certify, rather than as a noncompliance with a Federal motor vehicle safety standard that requires notification and remedy. There is no reason to regard the petitioner's failure to label its glazing with the DOT symbol in a different light.

The materials designation requirement ensures that the correct material will be used if the original glazing material has to be replaced. The designation that was not applied in this instance was "AS8". However, Standard No. 205 is permissive with respect to the type of glazing that may be used in the bottom of the rear door of school buses, and Thomas could have elected to use other types such as AS4 or AS1, the required glazing for windshields, in its original manufacture of the vehicle. Therefore, the agency has concluded that the failure to mark the rear glazing does not present a negative safety implication if the glazing is replaced by a type other than AS8. As the petitioner has noted, the glazing meets all other requirements for its type. Similar labelling failures were determined to be inconsequential after consideration of petitions submitted by Wayne Corporation (Docket No. IP86-7), and Cadillac Plastics & Chemical Company (Docket No. IP90-3).

Therefore, in consideration of the foregoing, it is found that the petitioner has met its burden of persuasion that the noncompliance described above is inconsequential as it relates to motor vehicle safety, and its petition is hereby granted.

Authority: 15 U.S.C. 1417; delegation of authority at 49 CFR 1.50 and 501.8.

Issued December 11, 1991.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 91-30021 Filed 12-16-91; 8:45 am]

BILLING CODE 4910-59-M

Research and Special Programs Administration

Applications for Exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applicants for exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Transportation has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo-only aircraft, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before January 16, 1992.

ADDRESS COMMENTS TO: Dockets Branch, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Branch, room 8426, Nassif Building, 400 7th Street, SW., Washington, DC.

NEW EXEMPTIONS

Application number	Applicant	Regulation(s) affected	Nature of exemption thereof
10710-N	Hawkins Chemical Inc., Minneapolis, MN	49 CFR 176.67(i), 176.67(j)	To authorize chlorine filled tank cars to stand with unloading connections attached during unloading without the physical presence of an unloader. (mode 2).
10712-N	City of Grand Rapids, Grand Rapids, MI	49 CFR 174.67(i)(j)	To authorize chlorine filled tank cars to stand with unloading connections attached during unloading without the physical presence of an unloader. (mode 2).
10713-N	Intercontinental Packaging Corporation, Tuckahoe, NY.	49 CFR 173.306	To manufacture, mark and sell a non-DOT specification polyethylene terephthalate plastic aerosol container with an inner flexible collapsible pouch for shipment of a nonflammable compressed gas. (modes 1, 3, 5).
10714-N	FIBA Compressed Gas Equipment, Westboro, MA.	49 CFR 173.304(a)(2)	To authorize the use of DOT Specification 3A, 3AAX and 3T cylinders forming part of a tube trailer or tube skids, for transportation of fluorocarbon trifluoromethane, classed as a non-inflammable liquified gas. (modes 1, 3).
10715-N	U.S. Department of Defense, Washington, DC.	49 CFR 173.88, 173.91	To authorize the transportation of Class B explosives and fireworks as part of aircrew survival gear. (mode 5).
10716-N	The West India Rum Refinery Ltd., Barbados, West Indies.	49 CFR 172.400(a), appendix B part 107, subchapter B.	To authorize the transportation of various distilled spirits, classed as flammable liquids, in non-DOT specification stainless steel portable tanks equipped with pressure and vacuum relief valves. (modes 1, 3).
10717-N	Union Tank Car Company, East Chicago, IN.	49 CFR 173.31, Retest Table 1	To extend retest provisions for specially designed DOT specification tank cars, which are in acid service and are over 22 years of age, from annually to 3 year intervals. (mode 2).
10718-N	Tesco Resources, Inc. Prospect, CT	49 CFR 173.3(c)	To authorize the manufacture, mark and sell of an emergency collapsible overpack container for use in transporting leaking containers from spill scenes. (modes 1, 2, 3, 4, 5).

Note: Notice of Application No. 10693–N Vertex Chemical Corporation that appeared at page 51747 of the **Federal Register** for October 15, 1991, should have appeared as follows:

To authorize chlorine filled tank cars to stand with unloading connections attached during unloading *without* the physical presence of an unloader.

Notice of Application No. 10701–N Kin-Tek Lab Inc. that appeared at page 57552 of the **Federal Register** for November 12, 1991, should have appeared 10719–N Kin-Tek Lab. Inc.

This notice of receipt of applications for new exemptions is published in accordance with part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on December 11, 1991.

J. Suzanne Hedgepeth,

Chief, Exemptions Branch, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 91–30023 Filed 12–16–91; 8:45 am]

BILLING CODE 4910–60–M

Applications for Modification of Exemptions or Applications To Become a Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of Applications for Modification of Exemptions or Applications to Become a Party to an Exemption.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier Federal Register publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "X" denote a modification request. Application numbers with the suffix "P" denote a party to request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before January 2, 1992.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

Application No.	Applicant	Renewal of exemption
9374–X	Poly Processing Company, Inc., Monroe, LA [1]	9374
9941–X	Thiokol Corporation—Huntsville Division, Huntsville, AL [2]	9941
10062–X	Callery Chemical Company, Pittsburgh, PA [3]	10062
10594–X	U.S. Department of Energy, Washington, DC [4]	10594
10706–X	Energy & Environmental Technology Company, Southfield, MI [5]	10706
10709–X	Exxon Chemical Company, Houston, TX [6]	10709

[1] To modify the exemption to authorize shipment of isothiazilone formulations without a need for venting or a restriction against bottom outlets.
[2] To modify exemption to authorize shipment of two additional Rocket Motor assemblies (Castor IVA) and Rocket Motor (Castor IVB).
[3] To modify the exemption to change the heater well on a welded steel cylinder from a schedule 80 stainless steel pipe to a "schedule 40" stainless steel pipe for shipment of potassium metal, classed as a flammable solid.
[4] To modify the exemption to clarify the reporting requirements relating to an incident during transportation.
[5] To reissue exemption originally issued on an emergency basis to authorize shipment of a flammable liquid contained in aluminum canisters overpacked in steel cylindrical packagings (missile containers).
[6] To reissue exemptions originally issued on basis to authorize shipment of certain mixtures of flammable and corrosive liquids in stainless steel DOT Specification 57 portable tanks.

Application No.	Applicant	Parties to exemption
6614–P	Mid-State Chemical & Supply Corp., Indianapolis, IN	6614
6614–P	Hasa of Arizona, Inc., Eloy, AZ	6614
6614–P	Cinderella, Inc., Saginaw, MI	6614
6691–P	McGinnis Welding Supply, Wichita Falls, TX	6691
6691–P	Capital Welding Supply Company, Little Rock, AR	6691
7909–P	DowBrands, Inc., Indianapolis, IN	7909
7909–P	Marion Merrell Dow, Inc., Cincinnati, OH	7909
7929–P	ECONEX, Inc., Pittsfield, IL	7929
8009–P	Southern California Gas Company, Los Angeles, CA	8009
8236–P	TAC Manufacturing, Inc., Jackson, MI	8236
8451–P	ECONEX, Inc., Pittsfield, IL	8451
8526–P	Certified Distribution Services, Inc., Cleveland, OH	8526
8526–P	Transport Corporation of America, Inc., Minneapolis, MN	8526
8556–P	Teisan Kabushiki Kaisha	8556
8627–P	Good Chemical & Testing Co., Inc., Hennessey, OK	8627
8723–P	Buckley Powder Company, East Englewood, CO	8723
8723–P	Ireco of Florida, Inc., Miramar, FL	8723
8966–P	Hasa of Arizona, Inc., Eloy, AZ	8966
9571–P	Teledyne McCormick Selph, Hollister, CA	9571
9607–P	International Lubrication Laboratories, Inc., Wichita, KS	9607
9610–P	Alliant Techsystems, Inc., New Brighton, MN	9610
9953–P	Burlington Motor Carriers, Inc., Daleville, IN	9953
9990–P	Alliant Techsystems, Inc., New Brighton, MN	9990
10298–P	Heli-Lift, Inc., Dallas, TX	10298

Application No.	Applicant	Parties to exemption
10504–P	Silicon Systems, Inc., Santa Cruz, CA	10504
10660–P	Chemsyn Science Laboratories, Lenexa, KS	10660

This notice of receipt of applications for renewal of exemptions and for party to an exemption is published in accordance with part 107 of the Hazardous Materials Transportation Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on December 11, 1991.

J. Suzanne Hedgepeth,

Chief, Exemptions Branch, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 91–30024 Filed 12–16–91; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

December 11, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms

OMB Number: 1512–0115.
Form Number: ATF F 5220.4.
Type of Review: Extension.
Title: Monthly Report—Export Warehouse Proprietor.
Description: Proprietors who are qualified to operate export warehouses that handle untaxpaid tobacco products are required to file a monthly report. This report summarizes all transactions by proprietors including receipts, dispositions and onhand quantities. ATF F 5220.4 is used for product accountability and is examined by regional office personnel.
Respondents: Businesses or other for-profit.
Estimated Number of Respondents: 195.
Estimated Burden Hours Per Respondent: 49 minutes.
Frequency of Response: Monthly.
Estimated Total Reporting Burden: 1,895 hours.

OMB Number: 1512–0192.
Form Number: ATF REC 5110/02 and ATF F 5110.11.
Type of Review: Extension.
Title: Distilled Spirits Plants Warehousing Records and Reports.
Description: The information collected is used to account for proprietor's tax liability, adequacy of bond coverage and protection of the revenue. The information also provides data to analyze trends, audit plant operations, monitor industry activities and compliance to provide for efficient allocation of field personnel plus provide for economic analysis.
Respondents: Businesses or other for-profit, Small businesses or organizations.
Estimated Number of Respondents/Recordkeepers: 243.
Estimated Burden Hours Per Respondent/Recordkeeper: 2 hours.
Frequency of Response: Monthly.
Estimated Total Reporting/Recordkeeping Burden: 5,832 hours.

OMB Number: 1512–0205.
Form Number: ATF REC 5110/01 and ATF F 5110.40.
Type of Review: Extension.
Title: Distilled Spirits Records (5110/01) and Monthly Report of Production Operations (5110.40).
Description: The information is used to account for proprietor's tax liability, adequacy of bond coverage and protection of the revenue. The information also provides data to analyze trends in the industry, and plan efficient allocation of field resources, audit plant operations and compilation of statistics for government economic analysis.
Respondents: Businesses or other for-profit.
Estimated Number of Respondents: 143.
Estimated Burden Hours Per Respondent: 2 hours.
Frequency of Response: Monthly.
Estimated Total Reporting Burden: 3,432 hours.
Clearance Officer: Robert N. Hogarth, (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, room 3200, 650 Massachusetts Avenue, NW., Washington, DC 20226.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 91–30056 Filed 12–16–91; 8:45 am]

BILLING CODE 4810–31–M

Public Information Collection Requirements Submitted to OMB for Review

December 11, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0069.
Form Number: CF 3461 and CF 3461 Alternate.
Type of Review: Reinstatement.
Title: Immediate Delivery Application.
Description: These form are used by importers and brokers to provide Customs with the necessary information in order to examine and release imported cargo.
Respondents: Businesses or other for-profit, Small businesses or organizations.
Estimated Number of Responses: 6,100.

Estimated Burden Hours Per Response: 8 minutes.

Frequency of Response: On Occasion.

Estimated Total Reporting Burden: 838,158 hours.

Clearance Officer: Ralph Meyer (202) 566–4019, U.S. Customs Service, Paperwork Management Branch, room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Department Reports Management Officer.

[FR Doc. 91–30057 Filed 12–16–91; 8:45 am]

BILLING CODE 4820–02–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–86]

Possible Action in Response to the People's Republic of China's Intellectual Property Laws, Policies, and Practices; Location of the Trade Policy Staff Committee (TPSC) Public Hearings

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice of public hearing location.

SUMMARY: On Monday, December 9, 1991, the Federal Register published a notice regarding a public hearing (56 FR 64280) to be held on January 6–7, 1992, and stated that the location would be announced at a later date. The public hearing will be held at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC. The hearing room will be posted at the entrance.

FOR FURTHER INFORMATION CONTACT: Questions about the public hearing should be directed to Ms. Carolyn Frank, Executive Secretary, Trade Policy Staff Committee, (202) 395–7210. Question about filing written testimony should be directed to Ms. Dorothy Balaban, Staff Assistant to the Section 301 Committee, (202) 395–3432.

David A. Weiss,

Chairman, Trade Policy Staff Committee.

[FR Doc. 91–30061 Filed 12–16–91; 8:45 am]

BILLING CODE 3190–01–M

Sunshine Act Meetings

Federal Register
Vol. 56, No. 242
Tuesday, December 17, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Friday, December 20, 1991.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets N.W., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

SUMMARY AGENDA: Because of their routine nature, no discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed 1992 Federal Reserve Bank pension supplement.
2. Publication for comment of proposed amendments to Regulation Z (Truth in Lending) relating to home equity lines of credit.

DISCUSSION AGENDA: Please Note That No Discussion Items Are Scheduled for This Meeting.

Note: If an item is moved from the Summary Agenda to the Discussion Agenda, discussion of the item will be recorded. Cassettes will then be available for listening in the Board's Freedom of Information Office, and copies can be ordered for $5 per cassette by calling (202) 452-3684 or by writing to:

Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: December 13, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-30167 Filed 12-13-91; 2:40 pm]

BILLING CODE 6210-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 10:15 a.m., Friday, December 20, 1991, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed acquisition of reader/sorters and peripheral equipment within the Federal Reserve System.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: December 13, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-30168 Filed 12-13-91; 2:40 pm]

BILLING CODE 6210-01-M

UNITED STATES INTERNATIONAL TRADE COMMISSION

TIME AND DATE: December 30, 1991 at 10:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings
2. Minutes
3. Ratification List
4. Petitions and complaints: Certain woodworking accessories (Docket Number 1662)
5. Inv. Nos. 731-TA-540, 541 (Preliminary) (Certain Welded Stainless Steel Pipes from Korea and Taiwan)—briefing and vote.
6. Any items left over from previous agenda

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary, (202) 205-2000.

Dated: December 12, 1991.

Kenneth R. Mason,

Secretary.

[FR Doc. 91-30191 Filed 12-13-91; 2:41 pm]

BILLING CODE 7020-02-M

NATIONAL LABOR RELATIONS BOARD

Notice of Meeting

TIME AND DATE: 9:30 a.m., Thursday, December 13, 1991.

PLACE: Board Conference Room, Sixth Floor, 1717 Pennsylvania Avenue, NW., Washington, DC 20570.

STATUS: Closed to public observation pursuant to 5 U.S.C. section 552 (c)(2) and (9)(B) (internal personnel matters and matters the premature disclosure of which would be likely to significantly frustrate implementation of proposed agency action).

MATTERS CONSIDERED: Staffing and internal casehandling procedures.

CONTACT PERSON FOR MORE INFORMATION: John C. Truesdale, Executive Secretary, National Labor Relations Board, Washington, DC 20570, Telephone: (202) 254-9430.

Dated: Washington, DC., December 12, 1991.

By direction of the Board:

John C. Truesdale,

Executive Secretary, National Labor Relations Board.

[FR Doc. 91-30166 Filed 12-13-91; 2:39 pm]

BILLING CODE 7445-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of December 16, 23, and 30, 1991 and January 6, 1992.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of December 16

Monday, December 16

10:00 a.m.
Briefing on Regulatory Application of PRA (Public Meeting)

Tuesday, December 17

10:00 a.m.
Briefing by DOE on Status of Civilian High Level Waste Program (Public Meeting)

Thursday, December 19

10:00 a.m.
Periodic Meeting with Advisory Committee on Nuclear Waste (ACNW) (Public Meeting)
11:30 a.m.
Affirmative/Discussion and Vote (Public Meeting) (if needed)
2:00 p.m.
Briefing on Status of Technical Specifications Improvement Program (Public Meeting)

Week of December 23—Tentative

There are no Commission meetings scheduled for the Week of December 23.

Week of December 30—Tentative

There are no Commission meetings scheduled for the Week of December 30.

Week of January 6—Tentative

Thursday, January 9

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To Verify the Status of Meeting Call (Recording)—(301) 504–0292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504–1661.

Dated: December 13, 1991.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 91–30221 Filed 12–13–91; 8:45 am]

BILLING CODE 7590–01–M

Corrections

Federal Register
Vol. 56, No. 242
Tuesday, December 17, 1991

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 235

State Administrative Expense Funds: National School Lunch Program, Special Milk Program for Children, School Breakfast Program, Child and Adult Care Food Program, Food Distribution Program

Correction

In proposed rule document 91-29196 beginning on page 63882 in the issue of Friday, December 6, 1991, make the following corrections:

1. On page 63884, in the table, in the 5th column, in the 21st and 22d entries, "5.000" should read ".5000".

2. On page 63885, in the 2d column, in the 2d paragraph, in the 19th line, "obligated" should read "unobligated".

3. On page 63889, in the 3d column, under the heading "State agency", in the 12th entry, "OK" should read "OR".

§ 235.4 [Corrected]

4. On page 63891, in the second column, in § 235.4, in amendatory instruction 4., paragraph d. was omitted. It should read as follows:

"d. Paragraph (b)(1) is amended by removing the words "For each fiscal year, FNS shall allocate " and the word "agency"."

5. On the same page, in the third column, in § 235.4(c), the last sentence was printed incorrectly. It should read as follows:

"The remaining funds shall be allocated to the State agency administering the child care component of the Child and Adult Care Food Program."

§ 235.11 [Corrected]

6. On page 63893, in the first column, in § 235.11:

a. In amendatory instruction b., in the third line, "§ 235.(4)(a)(1)" should read "§ 235.4(a)(2)".

b. In amendatory instruction c., in the third line, "§ 235.4(a)(2)" should read "§ 235.4(a)(1)".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91F-0424]

Sherex Chemical Co., Inc.; Filing of Food Additive Petition

Correction

In notice document 91-28606 appearing on page 61022 in the issue of Friday, November 29, 1991, make the following correction:

In the second column, in the **SUPPLEMENTARY INFORMATION**, in the fifth line, "Sherex" was misspelled.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N-0354]

New Monographs and Revisions of Certain Food Chemicals Codex Monographs; Opportunity for Public Comment

Correction

In notice document 91-28160, beginning on page 58910, in the issue of Friday, November 22, 1991, make the following correction:

On page 58910, in the third column, under **DATES:**, in the second line, "1991" should read "1992".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

Correction

In notice document 91-28103, beginning on page 58911, in the issue of Friday, November 22, 1991, make the following correction:

On page 58912, in the second column, in the first full paragraph, in the first line, "*One*" should read "*Open*".

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 220

[Docket No. R-91-1567; FR-3081-P-01]

RIN 2502-AF59

Smoke Detectors for HUD-Assisted or Insured Rental Housing and Public and Indian Housing

Correction

In proposed rule document 91-27952 beginning on page 59150 in the issue of Friday, November 22, 1991, make the following corrections:

On page 59152, in the second column, amendatory instruction 8, and the following section heading shoud read "Subpart C of part 220 would be amended by adding § 220.510 to read as follows:

§ 220.510 Smoke detectors."

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-940-4214-10; CACA 28888, CACA 28889, CACA 28890, CACA 28891, CACA 28892, CACA 28893, CACA 28894, CACA 28895, CACA 28896]

Proposed Withdrawals and Opportunity for Public Meeting; California

Correction

In notice document 91-24960, beginning on page 52053, in the issue of Thursday, October 17, 1991, make the following corrections:

1. On page 52053:

a. In the third column, in the land description, under T. 20 N., R. 11 E., in Sec. 28, "NE¼SE¼," should read "NE¼SE¼SW¼,".

b. In the same column, in the land description, under T. 19 N., R. 9 E., in

Sec. 1, "N½S¼SE¼." should read "N½S½SE¼."

c. In the same column, in the land description, under T. 18 N., R. 8 E., in Sec. 28, "N½N½NW¼SE¼†SE¼." should read "N½N½NW¼SE¼SE¼."

BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Antitrust Division

National Cooperative Research Notification; "Feasibility Study on Using Molecular Sieves for Diesel NO_x Control"

Correction

In notice document 91-26624, appearing on page 56528, in the issue of Tuesday, November 5, 1991, make the following correction:

On page 56528, in the 2nd column, in the 11th line from the bottom of the page, "Nisson" should read "Nissan".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 87-02; Notice 5]

RIN 2127-AE22

Federal Motor Vehicle Safety Standards; Seat Belt Assembly Anchorages

Correction

In proposed rule document 91-28996, beginning on page 63473, in the issue of Wednesday, December 4, 1991, make the following correction:

§ 571.210 [Corrected]

On page 63474, in the third column, in § 571.210, S 4.3.1.1(b), in the second line, "lime" should read "line".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 173

[Docket No. HM-198A; Amdt. Nos. 171-13, 172-125, 173-227, 174-69]

RIN 2317-AB31

Elevated Temperature Materials

Correction

In rule document 91-23468, beginning on page 49980, in the issue of Wednesday, October 2, 1991, make the following correction:

§ 173.247 [Corrected]

On page 49990, in the first column, in § 173.247(c)(3), in the sixth line, "(c)(l)" should read "(c)(1)".

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Part 3500

[Docket No. R-91-1558; FR-2955-P-02]

RIN 2502-AF24

Real Estate Settlement Procedures Act; Regulation X; Section 10 Escrow Account Statements

Correction

In proposed rule document 91-29390 beginning on page 64446 in the issue of Monday, December 9, 1991, make the following correction:

The "Initial Escrow Account Statement" appearing on page 64448, in the third column, and continuing on page 64449, in the first column, the first paragraph, is correctly printed below.

Initial Escrow Account Statement

An escrow account is being established to assure that certain obligations relating to the mortgaged property, such as taxes, insurance premiums and other charges, are paid. The escrow account may include charges that you have agreed voluntarily to have collected. This initial escrow account statement sets forth amounts to be collected, along with your principal and interest payments, to pay anticipated expenses during the first 12 months after your account is opened.

Date first escrow payment due: _____

Your escrow account payment will be $_____ per _____.

(month or other period)

Payee	Anticipated Date Due	Estimated Amount
_____	_____	$_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Estimated Annual Total Due: $_____

These figures are frequently estimates and may be subject to revision during the escrow account computation year. The escrow account normally continues outstanding during the life of the loan. Within 30 days after one year from the first escrow payment date set out above, you will receive an annual statement showing actual receipts and disbursements in your escrow account for the preceding year.

BILLING CODE 1505-01-D

federal register

Tuesday
December 17, 1991

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 10, et al.
New Animal Drugs; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, 16, 20, 500, 510, 511, and 514

[Docket No. 88N-0058]

RIN 0905-AA96

New Animal Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the regulations governing the approval, disapproval, and withdrawal of approval for marketing of new animal drugs. FDA is taking this action to make the agency's new animal drug approval process more efficient and to improve the agency's management of applications for marketing new animal drugs. The improvements will help applicants prepare and submit better quality applications and permit FDA to review them more efficiently and with fewer delays. This will benefit both the public and the applicants by facilitating earlier availability and marketing of safe and effective new animal drugs.

DATES: Comments by February 18, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8612.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Since 1981, FDA has been reevaluating and revising its regulations for investigational drugs and applications for marketing new drug products. The regulations governing the approval for marketing of new drugs and antibiotic drugs for human use (21 CFR part 314) were substantially revised through a notice of proposed rulemaking (47 FR 46622, October 19, 1982), followed by a final rule (50 FR 7452, February 22, 1985). (These revised regulations are referred to as the NDA Rewrite.)

In 1982, FDA's Center for Veterinary Medicine (CVM) commissioned a task force to review the agency's new animal drug regulations in 21 CFR part 514 with the intention of recommending revisions and streamlining the approval process for new animal drugs. The task force examined FDA's proposal of October 19, 1982, to revise the regulations governing applications for new human drugs and considered their applicability to the approval process for applications for new animal drugs. With certain exceptions, discussed below, the task force recommended that the changes proposed with regard to applications for new (human use) drugs be adopted with regard to applications for new animal drugs. A notice announcing the availability of the task force report was published in the Federal Register of May 20, 1983 (48 FR 22748).

As with the new (human use) drug regulations, this proposed rule for new animal drugs would be supplemented by a number of guidelines to provide specific advice for the collection and presentation of data and information to support approval of a new animal drug application (NADA). For example, format guidelines would address the summary and each of the different technical sections of the application. These guidelines would be in addition to the guidelines that CVM already has made available concerning the design of an adequate and well-controlled study.

Part 514 contains regulations governing applications for new animal drugs and for animal feeds bearing or containing new animal drugs. This proposed rule deals primarily with the approval, disapproval, and the withdrawal of approval for marketing of new animal drugs. Any final rule that is published based upon this proposal will contain a recodification/redesignation table showing how the current sections of the Code of Federal Regulations pertaining to animal feeds will be incorporated into the regulations for new animal drugs. (This proposed rule is also referred to as the NADA Rewrite.)

In a proposed rule published elsewhere in this issue of the Federal Register, FDA is proposing that certain revisions be made in the records and reports requirements for marketed animal drugs. Accordingly, in this proposed rule, FDA is only including a redesignation of § 510.305 as § 514.83 with no change in text.

II. Highlights of the Proposed Rule

The guiding principle of this proposed rule is that FDA's animal drug approval process should be efficient, but thorough, in order to facilitate the approval of new animal drugs that are shown to be safe and effective, to ensure the disapproval of new animal drugs that are not shown to be safe and effective, and to expedite the withdrawal of approval of new animal drugs that are no longer shown to be safe and effective. FDA encourages comments concerning any and all provisions of this proposed rule, including those provisions which differ from the new human drug regulations (21 CFR part 314). The major provisions of this proposed rule are summarized below:

A. Application Format

FDA proposes to follow the format adopted in the NDA Rewrite, codified at 21 CFR 314.50, with some modifications in the section headings and in the types of information to be included in the various sections. The new format would require an applicant to submit a summary of the entire application including labeling, and submit separate, detailed technical sections that contain the data, information, and analyses needed by each of FDA's reviewing disciplines. One of the principal causes of delay in FDA's review of applications is the unavailability of information essential to the agency's reviewers. A typical NADA for a new animal drug intended for use in food animals requires review by various types of scientists, including veterinarians, animal scientists, manufacturing chemists, microbiologists, medical specialists (e.g., parasitologists), residue chemists, toxicologists, environmental scientists, genetic toxicologists, and statisticians. Although NADA's are now submitted in three complete copies, a given reviewer might receive only the information in a particular volume or volumes related to his or her particular discipline and thus might not have in hand basic information on the composition, use, and labeling of the new animal drug under review. The proposed format would permit a complete, informed, and simultaneous review by each of the various scientific reviewers. In addition, the overall summary will facilitate review by CVM officials following completion of the individual review.

B. Safety Update Reports

FDA is proposing to require that new safety information received by the applicant following submission of the NADA be provided to FDA at key points in the review process (proposed § 514.50(d)(3)(ii)). Thus, FDA is proposing to require that the applicant provide to FDA safety updates 4 months following submission of the application, following receipt of an "approvable" letter, and at other times at FDA's request. These safety updates would ensure that FDA's decision on the NADA reflects the most current safety information available.

C. Human Food Safety

Animal drugs are commonly administered to animals used for food. Residues of the animal drugs may be present in the edible tissues or other products of the treated animals. For this reason, section 512(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(2)) requires that FDA, in determining whether a new animal drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, evaluate, among other things, the safety of "any substance formed in or on food" because of the use of the animal drug. See section 201(u) of the act (21 U.S.C. 321(u)), providing that the term "safe" as used in section 512 refers to the health of man or animal. FDA is proposing to set forth the requirements for establishing that a new animal drug will not cause unsafe residues in the edible tissues or other products of treated animals (proposed § 514.50(d)(4) and (5)).

D. Case Report Forms and Data Tabulations

This proposal differs significantly from the NDA Rewrite in that individual animal case report forms would be required to be submitted to FDA when applicable (proposed § 514.50(f)). There are good reasons for this difference from human drug evaluation. Human drug investigation is characterized by a number of strong safeguards to the patient, to ensure safety and confidentiality, adherence to protocols, and close clinical monitoring. The practice of veterinary medicine is not structured in a manner permitting such close control of animal subjects. There are two primary types of veterinary health care: (1) Herd or flock

management, and (2) individual animal care. The former generally involves large numbers of animals, usually receiving the drug as a group (e.g., in feed or water). Here, individual case report forms are rarely used. Rather, the performance, morbidity, and mortality are reported on the basis of the entire group of animals. FDA will continue to accept and review reports based upon herd or flock evaluations when applicable.

Individual animal treatment, on the other hand, is generally practiced on clinically ill animals or on companion animals in an out-patient clinic setting. Clinical laboratory results, to confirm diagnoses of the condition(s) being treated, are not always available and followup examinations are often not possible. Because of this variability in data gathering procedures, FDA is proposing to require that all case report forms describing individual animal treatment be submitted in the archival copy of the NADA. These reports, reviewed in conjunction with well-controlled laboratory studies, can provide the requisite evidence of the animal drug's safety and effectiveness under field conditions.

E. Environmental Assessment

The NDA Rewrite requires that applicants submit information on the environmental effects of drug manufacture in the manufacturing section of a new drug application but does not require information on the environmental effects of ultimate use. Animal drugs, however, often require an assessment of such effects. For example, drugs used in cattle or poultry can result in relatively large quantities of the drug or its metabolites entering the environment without intervening waste treatment. The environmental effects of such release must be carefully evaluated. For this reason, FDA is proposing to require that each NADA include a separate technical section for environmental data (proposed § 514.50(d)(8)) that is somewhat broader than that found in the NDA Rewrite, e.g., environmental effects information is required concerning ultimate use as well as manufacture.

F. Time Frames for FDA Review

FDA is proposing that, within 180 days from receipt of an application, the agency issue to the applicant an action letter, i.e., an "approval" letter, an "approvable" letter, or a "not approvable" letter, unless the 180-day period is extended through mutual agreement between the applicant and FDA. As is the case now, this time period could be extended if a major amendment is received, but FDA is proposing that the extension be only for the extra time needed to review the amendment. FDA is also proposing to allow the submission of a "minor" amendment without triggering any extension of the review time for the application.

FDA is proposing to define the procedure and time frame for "filing" an application within the meaning of section 512(b) of the act (21 U.S.C. 360b(b)) (proposed § 514.101). The current regulation (21 CFR 514.110) provides 30 days for the agency to refuse to file an application when it is obviously incomplete. In the agency's experience, 30 days has been an insufficient period in which to determine the acceptability of an application for "filing." FDA is proposing to provide 60 days for this initial review, a time sufficient to determine an application's acceptability and to either file the application or issue a refusal to file letter.

G. Foreign Data

FDA is proposing to incorporate current FDA policy with respect to the acceptability of foreign data in support of an NADA (proposed § 514.107). An NADA based solely on foreign clinical data may be approved by FDA if: (1) The foreign data reflect appropriate animal treatment in the United States, considering breeds, husbandry practices, environment, and disease patterns; (2) the studies have been conducted by qualified clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an FDA on-site inspection or, if FDA determines that such an inspection is necessary, FDA can validate the data through an on-site inspection or other appropriate means. Use of these criteria on a case-by-case basis would ensure the quality of any animal drug product approval based on foreign data, while removing the need to conduct repetitive clinical testing in this country in those instances where adequate data have been gathered abroad.

H. Action Letters

FDA is proposing to establish three types of FDA "action" letters on NADA's: An "approval" letter, an "approvable" letter, and a "not approvable" letter (proposed §§ 514.105, 514.110, and 514.120). The first is the same as the current "approval" letter. For dosage form animal drugs, and Category I Type A medicated articles that are not to be mixed with a Category II Type A medicated article, an "approval" letter grants marketing permission, and the effective date of the approval is the date of the "approval" letter. The current "incomplete" letter encompasses the proposed "approvable" and "not approvable" letters. The "approvable" letter would notify the applicant that the application may be approved when minor deficiencies are corrected. The "not approvable" letter would notify the applicant that major deficiencies exist, requiring the gathering of additional data/information or detailed new analyses of previously reported data.

As discussed below, for Category II Type A medicated articles, or a Category I Type A medicated article that is to be mixed with a Category II Type A medicated article, the effective date of the approval is the date of publication of the notice of approval in the **Federal Register**.

I. Communications Between FDA and Applicants

FDA is proposing to revise its policy for communications permitted between an applicant and FDA (proposed § 514.102). Under current policy, except in unusual circumstances, there is no provision for communication until all reviews have been completed and an "incomplete" letter has been issued. The proposal would encourage dialogue between an applicant and FDA about scientific and medical issues that arise during the review process. This dialogue would include notifying the applicant of easily correctable deficiencies in an application as they are found, and providing an opportunity to schedule informal conferences and for telephone contact during the review process and after FDA's review is completed.

FDA is also proposing to assign a "primary review division" upon receipt of the application (proposed § 514.100). That division would be the applicant's agency contact during the review process (see also proposed § 514.102(c)).

J. Dispute Resolution

FDA recognizes a need to codify a procedure for resolving disputes between an applicant and the agency. FDA is proposing to adopt the appeals procedure that CVM already uses to help resolve any disagreements over scientific and medical issues (proposed § 514.103). Proposed § 514.103 would supplement the general procedures set forth in 21 CFR 10.75.

K. Publication of Approvals

Section 512(i) of the act (21 U.S.C. 360b(i)) requires FDA to publish in the **Federal Register** all approvals of NADA's. Initially, FDA decided that the

date of approval for an NADA should be the date of publication in the Federal Register of the approval. Recently, FDA determined that, for dosage form drugs and Category I Type A medicated articles that are not to be mixed with a Category II Type A medicated article, no useful purpose was served by delaying the approval date beyond the date of the "approval" letter. FDA is proposing to codify the agency's current interpretation of the effective date of the approval of a dosage form drug and such a Category I Type A medicated article (proposed § 514.105(a)(1)). Approval of a Category II Type A medicated article and a Category I Type A medicated article that is to be mixed with a Category II Type A medicated article, however, will continue to become effective on the date of publication in the Federal Register of the "regulation" established under section 512(i) of the act reflecting the approval (proposed § 514.105(a)(2)). A Category II Type A medicated article is used in the subsequent manufacture of a Type B or Type C medicated feed. Such a feed cannot be manufactured or used unless it is in compliance with the regulations in 24 CFR part 558 and is the subject of a medicated feed application (MFA) approved pursuant to section 542(m) of the act (24 U.S.C. 360b(m)). The notice of approval of a Category II Type A medicated article published in the Federal Register establishes the necessary regulation in 21 CFR part 558 required for approval of an MFA.

L. Fewer Supplements to Approved Applications

FDA intends to substantially reduce the number of supplements to approved applications (supplemental NADA's) which must be submitted to the agency. FDA is proposing to establish different categories of supplemental NADA's (proposed § 514.70). FDA is proposing that, where an applicant seeks a change in the conditions of approval of an NADA that could affect the safety or effectiveness of an animal drug product, the applicant be required to submit a supplemental NADA which must be approved by FDA before the change is implemented. However, FDA is proposing that an applicant seeking other kinds of changes in the conditions of approval of an NADA may implement the changes and notify FDA afterwards. FDA estimates that the proposed rule, if promulgated, will result in a 20-percent reduction in the number of supplemental applications that require prior approval by the agency. FDA believes that establishing such categories of supplements should provide two advantages. First, it should permit applicants to implement a number of changes quickly without compromising animal drug safety or effectiveness. Second, it should facilitate more timely review in FDA of those changes which would still require prior approval.

Unlike the NDA Rewrite, the proposal would continue the requirement of prior approval of certain manufacturing changes. This difference is due to the nature of many animal drugs, their use, and administration. Although most animal drugs contain animal drug substances that are highly purified, Type A medicated articles may contain animal drug substances in the form of biomass products of low purity. Biomass products are derived from a fermentation process and are administered to animals as a complex mixture with no or only partial purification. Most of the biomass is comprised of mycelial fragments, metabolic products from the producing organism, media residues, and other compounds of unknown characteristics. For this reason, FDA performs a comprehensive initial safety review of biomass products. Manufacturing changes, especially new sources of the biomass, could have an adverse effect on the final product. Therefore, FDA proposes to continue to require prior approval of manufacturing changes involving animal drug substances that are biomass products.

M. Withdrawal of Approvals

Section 512(a)(1)(B) of the act (21 U.S.C. 360b(a)(1)(B)), provides that a new animal drug is unsafe unless the drug, its labeling, and its use conform to the approved NADA for the drug. This provision, and most notably its requirement that the use of a new animal drug conform to a NADA, has no express counterpart in section 505 of the act (21 U.S.C. 355), which applies to new (human use) drugs. FDA has tentatively concluded that, due to section 512(a)(1)(B) of the act (21 U.S.C. 360b(a)(1)(B)), significant misuse of an approved animal drug is a ground for withdrawing approval of an NADA under section 512(e)(1)(B) of the act (21 U.S.C. 360b(e)(1)(B)). Likewise, FDA has tentatively concluded that an animal drug is not shown to be safe for use within the meaning of section 512(e)(1)(B) of the act when new evidence shows that the drug is no longer shown to be safe by adequate tests by all methods reasonably applicable. FDA's interpretations of section 512(e)(1)(B) of the act are discussed further in section III C, paragraph 13a of this preamble.

N. Definition of New Animal Drug Substance

Following enactment of the Drug Amendments of 1962 (Pub. L. 87-781, 76 Stat. 780), FDA promulgated 21 CFR 130.1 (28 FR 6377, June 20, 1963), which set forth definitions applicable to new drugs and new drug substances. Section 130.1, which at the time applied to both new human and new animal drugs, stated: " 'New drug substance' means any substance that when used in the manufacture, processing, or packing of a drug causes that drug to be a new drug, but does not include intermediates used in the synthesis of such substances." Under § 130.1, the agency adopted a policy of permitting the unrestricted interstate shipment of bulk chemicals that were not in themselves drug substances but that could become such substances upon further chemical processing. Because interstate shipment includes export, such intermediates could be exported.

The Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 343-351) established a separate regulatory scheme for animal drugs, and prohibited the export of a new animal drug unless each of the requirements of sections 512 and 801(e) of the act (21 U.S.C. 360b and 381(e)) were met. In addition, when procedural regulations implementing the Animal Drug Amendments of 1968 were promulgated, the definition of new animal drug substance was not included (36 FR 18378, September 14, 1971). In view of the intent of Congress to prohibit export of unapproved new animal drugs (then section 801(d) of the act), the agency adopted a policy that intermediate substances intended for further processing into a new animal drug substance were themselves new animal drugs, and were therefore prohibited from export unless approved.

However, with the passage of the Drug Export Amendments Act of 1986 (Pub. L. 99-660, 100 Stat. 3743), it appeared that Congress intended to allow the export of intermediate drug substances upon FDA approval. Therefore, FDA is proposing to reinstate the definition of new animal drug substance removed in 1971. This reinstated definition would exclude intermediates used in the synthesis of such substances. This exclusion would have the effect of allowing the export of intermediate drug substances (proposed §§ 514.3(b) and 514.410).

III. Explanation of the Proposed Rule

Current Part 514—New Animal Drug Applications, has four subparts: Subpart A—General Provisions, Subpart B—

Administrative Actions on Applications, Subpart C—Hearing Procedures, and Subpart F—Judicial Review (Subparts D and E are reserved).

FDA is proposing to establish a new heading for part 514 and make major revisions and recodifications of these regulations.

FDA is proposing that the heading be "Part 514—Applications for FDA Approval to Market a New Animal Drug" and that the regulations contain six subparts: Subpart A—General Provisions describes the scope and purpose of the regulations and contains definitions of terms. Subpart B—Applications contains regulations about applications for new animal drugs and animal feeds bearing or containing new animal drugs and the responsibilities and rights of applicants concerning their applications. Subpart C—FDA Actions on Applications contains regulations about actions the agency takes on applications, including both applications under review and those already approved. Subpart D—Hearing Procedures for New Animal Drugs contains regulations on the procedures for hearings on proposals by CVM to withdraw or refuse approval of applications for new animal drugs and animal feeds bearing or containing new animal drugs. Subpart E—[Reserved]. Subpart F—Miscellaneous Provisions contains regulations stating FDA's policy on administrative issues that frequently arise concerning applications.

A. General Provisions

1. Scope of this Part (Section 514.1)

The proposed rule would apply to an application for marketing approval of a new animal drug or an animal feed bearing or containing a new animal drug. Excluded from the scope of the proposal are those animal drugs produced and distributed as biologics in full conformance with the Animal Virus, Serum, and Toxin Law of March 4, 1913 (37 Stat. 832 as amended (21 U.S.C. 151 *et seq.*)).

2. Purpose (Section 514.2)

The intent of the proposed rule is set forth in this section. The proposal is intended to facilitate the approval of any new animal drug that is shown to be safe and effective for its intended use, to ensure the disapproval of any new animal drug that is not shown to be safe and effective for its intended use, and to facilitate the withdrawal of approval of any new animal drug that is no longer shown to be safe and effective for its intended use.

3. Definitions (Section 514.3)

The proposed rule would define an *animal drug product* as a finished dosage form, such as a capsule, tablet, powder or solution, or a Type A medicated article, that contains an animal drug substance with or without one or more other ingredients. An "animal drug substance" would be defined as any active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of an animal's body. A "new animal drug substance" would be defined as any substance that when used in the manufacture, processing, or packing of an animal drug, causes that animal drug to be a new animal drug. As discussed above, the definitions would exclude intermediates used in the synthesis of the animal drug substance or the new animal drug substance. The exclusion of intermediates would apply only to intermediates that require some chemical change to produce the animal drug substance or the new animal drug substance. The exclusions would not apply to intermediates that require only purification or concentration to produce the animal drug substance or the new animal drug substance.

As used in 21 CFR part 514, the term "animal feed" would be defined to mean an animal feed bearing or containing a new animal drug as provided in 21 CFR part 558.

The term "applicant" would be defined to mean both a person who is seeking, and one who has obtained, FDA approval of an application. Under the current regulations, the terms "sponsor" and "applicant" are used interchangeably. In addition, the term "holder" is often applied to an applicant holding an approved application. As proposed, the term "sponsor" would be reserved for a person engaged in the investigation of a new animal drug as defined in 21 CFR 510.3(k). The term "holder" would be used only in reference to a drug master file. FDA is proposing use of the single term "applicant" to avoid confusion.

The proposed rule would also define "approval letter," "approvable letter," and "not approvable letter," terms the agency now uses to refer to action letters on new drug applications. An applicant may market a new animal drug upon the effective date of an "approval" letter received from FDA, unless the new animal drug is a Category II Type A medicated article (or a Category I that is to be mixed with a Category II), in which case the applicant may market the article upon the effective date of a "regulation" published in the **Federal Register** under section 512(i) of the act reflecting FDA's approval of the NADA. This difference in effective dates is necessary because of the requirement in section 512(m)(1)(B) of the act (21 U.S.C. 360b(m)(l)(B)) that an application to manufacture a Type B or Type C medicated feed identify the regulation (relating to the Category II Type A medicated article to be used in such feed), published pursuant to section 512(i) of the act, on which the applicant relies as a basis of approval of the application. That requirement cannot be met without publication in the **Federal Register** of a regulation showing the approval of the NADA for the Category II Type A medicated article to be used in the manufacture of the Type B or Type C medicated feed.

FDA believes that these proposed definitions will clarify the purpose of each action letter and make clear that action letters other than "approval" letters do not confer any rights to market an animal drug.

The term "application" is intended to apply to the full application described under proposed § 514.50, the application for an animal feed bearing or containing a new animal drug under proposed § 514.51, currently codified in § 514.2, and the minor use application described under proposed § 514.58. An "application" would include all amendments and supplements. FDA is not proposing any changes in the definitions of "minor use" and "minor species" in current 21 CFR 514.1(d)(1), but FDA is proposing to include these definitions in § 514.3.

B. Applications

In § 514.50, the agency is proposing substantial changes in the content and format requirements for NADA's. The proposed changes are intended to reduce significantly the amount of information applicants must submit, improve the quality of their submissions through greater use of summaries and analyses, and expedite FDA's review.

The agency will issue guidelines to assist applicants with the requirements stated in § 514.50. Such guidelines do not themselves establish requirements; an applicant may choose to follow an alternative procedure. These guidelines will not necessarily be issued under § 10.90(b) (21 CFR 10.90(b)). FDA is considering whether to revise that section. In the meantime, the agency will continue issuing guidelines, but they will not bind FDA or any other person in any way, nor will they create or confer any

rights, privileges, or benefits for or on any person.

1. Content (Section 514.50(a))

The current content requirements for an NADA are contained in a two-part form, Form FDA 356V and 357V. Form FDA 356V is a checklist application form which advises FDA of what is being submitted. The form must be signed by the applicant or by a U.S. agent of the applicant, if the applicant resides outside the United States. Form FDA 357V lists the information that is set out in the current regulations and that is required for an NADA submission. Form FDA 357V need not be submitted by the applicant. If proposed § 514.50 is promulgated, Form FDA 356V will be revised accordingly and Form FDA 357V will be eliminated.

2. Format (Section 514.50(h))

The current format of the application is unnecessarily burdensome for applicants to prepare and for the agency to review. An applicant must submit to FDA three copies of the complete application. FDA then divides its review of the application into five review areas: Chemistry, manufacturing, and controls; effectiveness; animal safety; environmental impact; and bioavailability. If the new animal drug is to be used in food-producing species, FDA also reviews residue chemistry and residue toxicology data. In addition, if the new animal drug is an anti-infective, the agency conducts a microbiology review. FDA is proposing that applicants prepare an application that is in a format that facilitates concurrent reviews by the different scientific disciplines.

The agency proposes to require two complete copies of an application, an archival copy and a review copy, and a second review copy of the "chemistry, manufacturing, and controls" technical section of the application. The archival copy (§ 514.50(h)(1)) would be a complete copy of the application including case report forms and tabulations. The review copy (§ 514.50(h)(2)) would consist of separately bound sections that could be distributed for concurrent review in each reviewing unit. Both complete copies of the application would contain six to eight technical sections, one for each of the specific review areas. Each technical section in the review copy would contain a copy of a revised Form FDA 356V, the technical and scientific information needed by the specific review area, and a copy of the summary of the complete application. A summary would not be required for certain supplements. The second review copy of the "chemistry, manufacturing, and controls" technical section would be required to facilitate preapproval inspection of the manufacturing facility. That proposed requirement reflects the proposed preapproval inspection requirements for human drugs that were published in the **Federal Register** of January 28, 1991 (56 FR 3180).

Proposed § 514.50(h) would reduce the amount of paperwork applicants would be required to submit to FDA, provide each reviewing unit with an overview of the entire application, as well as the specific data the unit is charged with reviewing, and give each reviewer access to the complete application. Proposed § 514.50(g)(3) would also provide for submission of certain kinds of data via microfiche or electronic media, upon agreement between the applicant and the agency.

3. Summary (Section 514.50(c))

The application summary would contain an abstract of all the information in the application and would provide reviewers in each review unit and CVM officials with a good general understanding of the new animal drug. The summary would contain an annotated copy of the proposed labeling for the new animal drug, a discussion of the new animal drug's benefits and risks, a description of the foreign marketing history of the new animal drug (if any), and a summary of each technical section. The description of the foreign marketing history would permit FDA to contact foreign regulatory officials about their experiences with the new animal drug and, depending on the facts and circumstances, expedite approval in this country of important new animal drugs that are already available in other countries.

The agency believes that a good summary that integrates all the information in an application would contribute most to assisting FDA in reaching a decision on the application. The agency intends to prepare and make available guidelines describing the preparation of a summary and each of the technical sections.

The proposed rule would require the applicant to submit an archival copy of the application that contains a single copy of the application form, the summary, an index, and a copy of each review area's technical section. The archival copy would also contain copies of tabulations and case reports, and labeling. Samples of the new animal drug would be submitted if requested by FDA. The applicant may submit specified portions of the archival copy on microfiche, but the applicant may not submit tabulations and case report forms on microfiche unless the applicant and the agency agree to such submission.

During the review of the application, the archival copy would serve as a reference source for reviewers to find information not contained in the technical sections they receive, a reference source for agency officials, and the repository of the copies of tabulations and case report forms on the clinical studies. Each section of the review copy would be used by a primary or consulting reviewer for simultaneous review. A second review copy of the "chemistry, manufacturing, and controls" technical section would be provided to an FDA field office for its use in conducting a preapproval inspection of the manufacturing facility. After an application is approved, the review copy would either be destroyed or parts of it would be provided to other FDA offices for reference.

After approval of an application, the archival copy would serve as the agency's sole copy of the approved application for monitoring the safety, effectiveness, and labeling of the new animal drug; the focus of supplements and changes contained in the annual reports; and a source of documents for release under the agency's public information regulations in 21 CFR Part 20 and proposed § 514.430.

4. Colored Binders (Section 514.50(h)(2)).

The agency now furnishes colored binders to applicants free of charge for organizing their applications. By providing such binders, FDA establishes a standard color set. FDA would continue to do so under this proposal because the agency has found that its document control units can file and distribute submissions to appropriate offices more quickly and with fewer mistakes if uniform colored binders are used for each section of the submission. Also, if a section is misrouted, the color of the binder quickly alerts the recipient to the mistake. Although proposed § 514.50(h)(2) would not require applicants to use the agency's binders, FDA believes that their use will expedite review of applications.

5. Information Incorporated from a Drug Master File (Section 514.420).

The agency proposes to continue its current practice of permitting an applicant to incorporate into an application information that the applicant has previously submitted in a drug master file (described below) or in other applications, without resubmission of the information to the agency. The

incorporation must specifically identify the FDA file where the agency can find the information.

If an applicant incorporates information submitted to the agency by another person, the applicant must obtain and include in the application a written statement from that person authorizing the incorporation.

6. Foreign Language Submissions (Section 514.50(g)(2)).

The agency would also retain the current requirements that an application contain an accurate and complete English translation of each part of the application that is in a foreign language and a copy of each original literature publication for which an English translation is submitted.

7. Contents of Review Copy of Application.

As noted above, the review copy of the application would consist primarily of six to eight separate sections containing the technical and scientific information that FDA reviewers need to conduct their reviews. Each review copy would also contain a signed Form FDA 356V, a summary of the application, and a copy of all the labeling for the product. A description of the proposed requirements for each of the technical sections follows:

a. *Chemistry, manufacturing, and controls section (§ 514.50(d)(1)).* This section would describe the composition manufacturing methods, specifications, and test methods used for the animal drug substance and the animal drug product. Under the NDA Rewrite, the environmental impact analysis for a new drug is contained in this section. Under this proposal, such an analysis for a new animal drug would be contained in its own technical section (section III B, paragraph 7h of this preamble).

FDA proposes to eliminate certain of its requirements with respect to the information that an application must contain about manufacturing practices that are the subject of the agency's current good manufacturing practice (CGMP) regulations in 21 CFR part 211 or 21 CFR part 226. The CGMP regulations were promulgated in 1963 and updated substantially in 1975 and 1986 for Type A medicated articles and in 1978 for finished pharmaceuticals. The CGMP regulations set comprehensive standards for animal drug product manufacturing. FDA enforces these standards through statutorily required on-site inspections of animal drug manufacturers and through other means.

FDA is proposing that the following information currently required under 21 CFR 514.1(b)(5) no longer need be submitted in an application, because the agency already has access to the information in reports of establishment inspections conducted to determine compliance with the CGMP regulations:

(1) A description of the physical facilities;

(2) A description of the qualifications and responsibilities of technical and professional personnel;

(3) Information about the method of preparation of the master formula records and individual batch records, and a statement about the manner in which the records are used;

(4) Information about the number of individuals checking the weight or volume of each individual ingredient in each batch of the new animal drug, information about whether the total weight or volume of each batch is determined at any stage of the manufacturing process, and information about precautions taken to check actual package yield produced from a batch of a new animal drug with the theoretical yield; and

(5) Information about precautions taken to ensure that each lot of the new animal drug is packaged with the proper label and other labeling.

Information relevant to equipment used in the manufacturing process and an explanation of the lot control number system for raw materials and animal drug products would still be required to be submitted.

The agency also proposes to require that applications continue to contain the following information about the animal drug substance and the animal drug product.

i. *Animal drug substance (§ 514.50(d)(1)(i)).* The agency proposes to require that the applicant continue to submit the following information about the animal drug substance: (1) A full description of the animal drug substance, including its physical and chemical characteristics and stability; (2) the name and address of its manufacturer; (3) the method of synthesis (or fermentation or isolation) and purification of the animal drug substance; (4) the process controls used during its manufacture and packaging; and (5) the specifications and analytical methods needed to assure the identity, strength, quality, and purity of the animal drug substance and the bioavailability of the animal drug product made from the substance. Under proposed § 514.50(d)(1)(i), an applicant may refer to the current edition of an official compendium or to a master file to satisfy some of these requirements.

ii. *Animal drug product (§ 514.50(d)(1)(ii)).* The agency proposes to require that the applicant continue to submit the following information about the animal drug product that is the subject of the application: (1) A statement of the composition of the animal drug product and a list of all components used in the manufacture of the animal drug product, regardless of whether they actually appear in the animal drug product (for example, even if they are removed during processing they would nevertheless have to be listed); (2) a statement of the specifications and analytical methods for each component; (3) the name and address of the animal drug product manufacturer with (a) a list of manufacturing and laboratory equipment, and (b) an explanation of the raw material and batch control number system; (4) a description of the manufacturing production record and packaging procedures and in-process controls for the animal drug product; (5) the specifications and analytical methods that are necessary to assure the identity, strength, quality, purity, and bioavailability of the animal drug product; and (6) stability data necessary to establish an expiration date for the animal drug product. Under proposed § 514.50(d)(1)(ii), an applicant may refer to the current edition of an official compendium or to a master file to satisfy some of these requirements.

b. *Effectiveness section (§ 514.50(d)(2)).* Clinical data and information are generally gathered from studies of the new animal drug in the species or class of animals for which approval for marketing is being sought. The proposal would change little of the substance of the current requirement that an application contain a description and analysis of each study conducted to evaluate the effectiveness of the new animal drug, including: Each controlled dose determination study, each controlled dose confirmation study, each controlled clinical study, each uncontrolled clinical study, and all other information relevant to an evaluation of a new animal drug's effectiveness. When needed, the application would also have to contain a description of the statistical analyses of the controlled studies. In addition to the description and individual analyses, the proposed rule would also require the applicant to prepare an integrated analysis of all the clinical information about the new animal drug.

c. *Target animal safety section (§ 514.50(d)(3)).* The proposal would require that the application contain a description and analysis of each

nonclinical and clinical pharmacology study to determine the safety of the new anima1 drug, including a brief comparison of the results of the target animal studies with the laboratory animal pharmacology and toxicology data. In addition, the proposed rule would require the application to contain a description and analysis of any other data or information relevant to an evaluation of the safety of the animal drug in the target species. Such data or information would include any information received by the applicant from any source, foreign or domestic, such as information resulting from clinical investigations, controlled or uncontrolled studies of a use of the animal drug other than the use proposed in the application, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

In § 514.50(d)(3)(ii), the agency proposes to add one new requirement. FDA is proposing to require that an applicant submit safety information from ongoing animal studies at specified times following submission of the NADA. This new provision is consistent with the requirement of safety update reports in the NDA Rewrite, and is based upon the same concerns. Although new safety information obtained from clinical or nonclinical studies is currently required to be submitted to FDA with respect to an investigational new animal drug (INAD), such information is not now required to be submitted with respect to a pending NADA, unless specifically requested by the agency. Although FDA reviewers routinely examine the INAD as an integral part of the NADA review, this examination normally occurs early in the review process. Submissions of safety information by the applicant later in the review period may not now come to the attention of the reviewer in a timely manner.

Accordingly, the proposed change would require that applicants periodically submit updated safety reports describing new information about the new animal drug. These periodic updated safety reports would include the same kinds of information and would be submitted in the same format as would be required in the original application. Under the proposal, these reports would be required to be submitted 4 months after the original submission of the application, after receipt of an "approvable" letter, and at other times as requested by FDA. Applicants are encouraged to consult with agency officials prior to submission of the first safety update report.

d. *Residue toxicology section (§ 514.50(d)(4)).* In this section, the agency is proposing requirements for the toxicology studies for a new animal drug intended for use in animals raised for food production. Residues of the animal drug may be present in the edible products of those animals. The data from the toxicology studies establish the safety of residues of the new animal drug including its metabolites and any other substances formed in or on food because of the use of the drug (section 512(d)(2)(A) of the act (21 U.S.C. 360b(d)(2)(A)). The studies in question include acute, subacute, and chronic toxicity; carcinogenicity; reproductive toxicity and teratogenicity in several mammalian species; and genetic toxicology. A determination by FDA that the new animal drug may be or is a carcinogen when subjected to these tests will trigger some or all of the requirements of subpart E of 21 CFR part 500.

The studies identified above represent the full range of toxicity tests that may be required to enable the agency to determine whether the residues which may be incurred in food because of use of the new animal drug are safe. These studies may not be required in each application for a given new animal drug proposed for use in food-producing animals. FDA has prepared a guideline describing a data collection scheme that makes possible an agency decision regarding residue safety without the necessity of the applicant always performing all the studies identified. This guideline would remain in effect after publication of a final rule based on this proposal.

e. *Residue chemistry section (§ 514.50(d)(5)).* In this section, the agency is proposing requirements for determining the quantity and characteristics of residues of the new animal drug in the edible products of treated animals. This section would require the application to contain the method proposed by the applicant for the detection and measurement of residues of the new animal drug and its metabolites and any other substances formed in or on food as a result of use of the new animal drug, or, in the case of a new animal drug that is not a carcinogen or a possible carcinogen, data or other adequate information to establish that it is not reasonable to expect the animal drug or its residues to become a component of food at concentrations deemed to be unsafe.

The residue chemistry section of the application would also have to contain data and information on the absorption, distribution, metabolism, and excretion of the animal drug in laboratory animals as well as in the target species.

FDA will evaluate the data from the residue toxicology and residue chemistry studies together with the data from the residue depletion studies. All these data will be evaluated by the agency to determine the conditions of safe use of the new animal drug from the standpoint of human food safety. The agency will determine the safe concentrations of the new animal drug and its metabolites and any other substances formed in or on food because of the use of the drug and either publish an appropriate tolerance or establish safe concentrations for such residues. FDA may also require a withdrawal period or other use restriction to ensure human food safety.

In the case of a carcinogenic or possibly carcinogenic new animal drug, the proposed rule would retain the current requirement that the drug satisfy the applicable provisions of subpart E of 21 CFR part 500.

f. *Pharmacokinetics and bioavailability section (§ 514.50(d)(6)).* In this section, FDA is proposing requirements for pharmacokinetics and bioavailability studies. The data from these studies will enable FDA to determine the bioavailability and distribution of the new animal drug product in the target species to ensure that the new animal drug will have the effect it is purported to have. The bioavailability studies would provide an in vivo test of the assumptions made when testing the animal drug in vitro as part of the manufacturing and controls development.

g. *Microbiology section (§ 514.50(d)(7)).* For an anti-infective new animal drug, the agency proposes to require that the application contain a separate section with information, based on microbiological data, about the anti-infective properties of the new animal drug. The proposed requirements would not differ from those now in effect but would simply ensure that the requisite data are included in a discrete section of the application. The microbiology section would include information about the new animal drug's microbial action, including the biochemical basis of the new animal drug's actions, its antimicrobial spectrum, and the results of in vitro studies that show the concentrations of the new animal drug needed to affect that spectrum. This section of the application would also be required to contain information about mechanisms and prevalence of microbial resistance to the new animal drug and a description of clinical laboratory tests

(for example, in vitro susceptibility products) needed for effective clinical use of the new animal drug. Finally, the microbiology section would have to contain certain information required of anti-infective drugs subject to 21 CFR 558.15, namely, antibiotic, nitrofuran, and sulfonamide drugs intended for continuous low level (i.e., subtherapeutic) administration in animal feeds. These drugs require testing to ensure that their subtherapeutic use in animals does not result in a reservoir of drug-resistant organisms that could be hazardous to humans.

h. *Environmental impact section (§ 514.50(d)(8)).* FDA is proposing to retain the requirement that an application contain either a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment prepared under 21 CFR 25.31 analyzing the environmental impact of the manufacturing process and the ultimate use of the new animal drug product. (Part 25 contains FDA's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*, as amended).) The claim for categorical exclusion or the environmental assessment must be accompanied by documentation supporting the claim or the conclusions reached regarding environmental impact.

8. Contents of Archival Copy of Application

As explained above, the archival copy of the application would contain copies of the technical sections, the application Form FDA 356V, the summary, an index, all labeling components, and the following additional sections:

a. *Samples and labeling (§ 514.50(e)).* The agency proposes to retain the requirement that the applicant submit samples of the finished animal drug product, the animal drug substance used in the manufacture of the animal drug product, and reference standards and blanks. However, FDA is proposing to reduce the applicant's burden of submitting samples of the finished animal drug product by requiring the submission of samples only if specifically requested by FDA. FDA is also proposing to reduce the number of copies of proposed and final printed labeling for the animal drug product.

b. *Case report forms and tabulations (§ 514.50(f)).* FDA is proposing to reduce the amount of paperwork an applicant is required to submit in an application by requiring the submission of copies of the individual case report forms only in the archival copy of the application. The agency proposes to require the submission of tabulations of the data from the individual case report forms in both the review copy and the archival copy. The tabulations put the data and information gathered in the clinical studies in a more condensed and more easily reviewed form. Thus, the submission of tabulations instead of case report forms in the review copy is expected to reduce the time needed to review the application. The reviewer would still have access to the individual case report forms in the archival copy.

9. Application for an Animal Feed Bearing or Containing a New Animal Drug (Section 514.51)

FDA is more clearly stating current procedures for the processing of applications for animal feeds bearing or containing new animal drugs (medicated feed applications or MFA's, also known as Form FDA 1900's).

10. Abbreviated Application

An abbreviated new animal drug application can be filed under certain conditions based on either a pre- or post-1962 approved "pioneer" product. The statutory authority for an abbreviated application based on either a pre- or post-1962 "pioneer" product is as follows:

a. *Drug Amendments of 1962, Drug Efficacy Study Implementation (DESI) Program.* In 1962 Congress amended the new drug approval provisions of the act (which then applied to new drugs intended for both man and other animals) to require that an animal drug be shown to be both safe and effective before marketing (the Drug Amendments of 1962, Pub. L. 87–781, 76 Stat. 780). Before 1962, an animal drug had to be tested to show only its safety. Under the 1962 amendments, the effectiveness requirement was made applicable, after a 2-year transitional period, to new animal drugs approved before 1962. To implement this congressional mandate, FDA undertook an evaluation of new animal drug products that had been approved before October 10, 1962, to determine whether there was substantial evidence of effectiveness for each such product for each of its indications. FDA, relying largely on reviews conducted by the National Academy of Sciences and National Research Council (NAS/NRC), established a pre-1962 drug evaluation program known as the Drug Efficacy Study Implementation (DESI) program. Under the DESI program, an NADA approved before October 10, 1962, could continue to be approved if the sponsor submitted a supplemental NADA to revise the indications for use to those FDA had determined to be effective.

There were also marketed animal drug products for which no application had been filed but that were identical, similar, or related to the new animal drug products found effective in the DESI review. These identical, similar, or related animal drug products, commonly referred to as "me-too" animal drug products, were duplicate versions of pre-1962 approved "pioneer" products. In many cases, FDA policy had allowed these "me-too" animal drug products to be marketed without approved applications or without any notification to the agency. This policy was invalidated in 1975 (*Hoffmann La-Roche, Inc.* v. *Weinberger*, 425 F. Supp. 890 (D.D.C. 1975)).

FDA had already established the abbreviated application to provide an appropriate procedure for such products to obtain FDA approval based in part on the DESI evaluation. Each **Federal Register** notice announcing the effectiveness conclusion reached in the DESI review included, when appropriate, an FDA finding that an abbreviated application was the suitable mechanism by which manufacturers or suppliers of "me-too" new animal drug products could obtain FDA approval. Following a finding of effectiveness under the DESI program, manufacturers of "me-too" products subject to the finding were required to submit and obtain FDA approval of an abbreviated application. Other manufacturers who subsequently decided to market a "me-too" animal drug product were also required to submit and obtain FDA approval of an abbreviated application.

An abbreviated application, unlike a full application, was not required to include extensive target animal safety and effectiveness data and information on the new animal drug product. Rather, the abbreviated application, in the usual circumstance, had to establish that the new animal drug product covered by the application was equivalent in target animal safety and effectiveness (generally by bioavailability data) to the "pioneer" product that has undergone DESI review. The effectiveness of the new animal drug was already determined on the basis of the information reviewed as part of the DESI process. The agency's conclusions, which could be relied upon by all marketers, were stated in the DESI notices. The target animal safety of the new animal drug was determined on the basis of the approval and marketing experience of the "pioneer" product. Thus, the information required to be in an abbreviated application was usually limited to information about the

applicant's ability to manufacture a product of acceptable quality, and about total residue depletion.

The agency specified in the animal drug regulations which animal drugs were eligible for abbreviated applications.

An abbreviated application for a "me-too" animal drug product (a generic equivalent of any pre-1962 approved "pioneer" product) ordinarily will not be approved under the DESI program, but will be considered for approval under the Generic Animal Drug and Patent Term Restoration Act. Such an application will not be approved where the "pioneer" has not conformed to the applicable DESI notice.

b. *Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988.* On November 16, 1988, the Generic Animal Drug and Patent Term Restoration Act of 1988 was enacted (Pub. L. 100–670, 102 Stat. 3971). GADPTRA amended the act to authorize abbreviated new animal drug applications, and title 35 of the United States Code to authorize the extension of patents for animal drug products. At the time of enactment, the agency accepted certain abbreviated applications only for those animal drug products which were duplicates of drug products that were approved on the basis of safety prior to October 10, 1962, the date of enactment of the Drug Amendments of 1962, and which were subsequently found effective in the DESI program. (See section III B, paragraph 10a of this preamble.)

GADPTRA requires the agency to promulgate regulations to implement its provisions. There is a transitional provision which directs the agency to apply the human drug regulations for abbreviated applications at 21 CFR 314.55, and for bioavailability and bioequivalence at 21 CFR part 320, to the extent such regulations are not inconsistent with GADPTRA. FDA considered including proposed implementing regulations in this proposal. After reviewing GADPTRA, FDA decided that it would be premature to do so at this time. There are a number of issues to be resolved and procedures to be developed before proposed regulations implementing GADPTRA can be issued.

To provide guidance, however, FDA has issued several policy statements on GADPTRA. Before promulgating regulations FDA will, if needed, issue additional policy statements to implement GADPTRA.

c. *Effect of GADPTRA on Approval of Pre-1962 Drugs Under the DESI Program.* GADPTRA provides for the generic duplication of "pioneer" new animal drug products that have been approved for safety and effectiveness by FDA. The new law, therefore, covers drugs that were approved for safety by FDA prior to 1962, and subsequently approved for effectiveness under the DESI program. FDA has approved generic duplicates of such drugs under the DESI program for a number of years. Requirements and procedures for approval of generic drugs under the DESI program differ in some respects from those for approval of generic drugs under GADPTRA.

FDA was not permitted to approve abbreviated NADA's (ANADA's) for generic animal drugs under GADPTRA until January 1, 1991. In passing GADPTRA, Congress did not explicitly revoke the authority for FDA to approve generic duplicates of pre-1962 drugs under the DESI program. Now that generic drugs may be approved under GADPTRA, however, FDA does not intend to have two separate programs or policies for the approval of such drugs, and FDA will no longer accept DESI applications for generic new animal drugs. Generic equivalents of pre-1962 new animal drugs will now be approved under GADPTRA, except that FDA will approve as a DESI application, such an application that was pending on December 31, 1990, provided that the applicant has exercised due diligence in pursuing the approval and continues to do so. FDA's current bioequivalence guidelines for new animal drugs will be applied to all pending DESI applications, unless commitments have already been made for different bioequivalence requirements.

11. Minor Use Application (Section 514.58)

The agency proposes to redesignate, with editorial changes only, the provisions in current § 514.1(d) regarding a minor use application.

12. Amendment of an Unapproved Application (Section 514.60)

The proposed provisions regarding submission of an amendment to a pending application are substantially different from current agency policy. The current policy is that any substantive amendment submitted to an application, whether at FDA's request or on the applicant's own initiative, automatically restarts FDA's 180-day review clock, resulting in a new review cycle. Under the proposal, extensions to the review clock for evaluating major amendments would be limited to the time necessary for FDA to review them. An amendment would be classified as major if it would require a substantial amount of time to review; for example, a major amendment might contain significant new data from a previously unreported study or detailed new analyses of previously reported data. Normally, the submission of updated safety information under proposed § 514.50(d)(3)(ii) would not constitute a major amendment of the application.

The agency would consider the submission of a major amendment to constitute an agreement by the applicant to an extension of the review period, but, as noted above, only for the length of time needed for FDA to review the submission.

The director of the CVM primary review division would determine the extent of the extended review period, up to a maximum of 180 days. The division director would then inform the applicant of the length of the extension.

An applicant who disputes the length of the extension provided by the division could request FDA's reconsideration (see proposed § 514.103). This proposed change should significantly reduce the amount of time FDA would have to review applications because most applications are amended at some point during the review process.

13. Withdrawal by the Applicant of an Unapproved Application (Section 514.65)

This proposed section is substantially the same as current §§ 514.7 and 514.100(g), with one change. The proposal would provide that a pending application would be considered to be withdrawn if the applicant has not responded to an "approvable" letter or a "not approvable" letter within 60 days.

14. Supplements and Other Changes to an Approved Application (Section 514.70)

With few exceptions, any change in the conditions originally approved by FDA in an application was formerly required to be approved by the agency in a supplemental application before the change could be implemented. With respect to some changes, particularly those concerning manufacturing practices, this requirement seemed to be unnecessary. Further, review of supplements diverted FDA reviewers from more important work and caused applicants to defer making beneficial changes in approved products until the supplement was approved. For these reasons, CVM reviewed its supplemental application policy and identified changes that would no longer require prior FDA approval. By letter dated February 20, 1987, FDA notified each of the sponsors of approved applications listed in 21 CFR 510.600 of

the changes that could be made in an approved application and placed into effect before receiving agency approval. In proposed § 514.70, FDA would codify the policy described in the 1987 letter.

Under § 514.70, an applicant's proposed changes in the conditions in NADA's as currently approved would fall into one of three categories: (1) Those changes requiring prior FDA approval of a supplement before implementation; (2) those requiring a supplement but for which FDA approval prior to implementation is not necessary; and (3) those requiring reporting to FDA in a periodic drug experience report instead of a supplement. FDA is proposing to retain preclearance requirements for those changes in conditions of approval for animal drugs that could affect the safety or effectiveness of the animal drug. Proposed § 514.70 would permit applicants to implement certain changes sooner.

Whether data in the parent NADA will require reevaluation before a supplement may be approved depends on the nature of the supplement. Assignment of review categories for those changes that ordinarily will not require reevaluation of the safety or effectiveness data in the parent NADA and those that may require reevaluation of certain portions or all of the data in the parent NADA are described in current § 514.106, as promulgated in the Federal Register of November 1, 1990 (55 FR 46045), which is being included in this proposal for the sake of completeness, rather than for comment.

a. *Supplements requiring FDA approval before the change is made (§ 514.70(b)).* The agency proposes to retain requirements that the applicant submit a supplemental application and obtain FDA approval before making any of the following changes in the conditions in an approved application:

(1) A change in the synthesis, fermentation, or isolation of the animal drug substance;

(2) A change affecting either the animal drug substance or the animal drug product to relax the limits for a specification, establish a new analytical method, or delete a specification or analytical method;

(3) A change in the animal drug product to delete or add an ingredient or otherwise to change the composition of the product (other than deletion of an ingredient intended to affect only the color of the product);

(4) A change in the method of manufacture of the animal drug product;

(5) The use of a different facility or establishment to manufacture, process, or package and label the animal drug product;

(6) The use of a different facility or establishment to manufacture, process, or package the animal drug substance in any one of several circumstances, including where the manufacturing process in the new facility or establishment differs from that approved in the application; where the new facility or establishment has not received a satisfactory CGMP inspection within the previous two years covering that facility or establishment; and where the animal drug substance is intended to be administered to animals as a biomass product;

(7) A change in the animal drug product container and closure system or in a specification or analytical method for the system;

(8) Any change in the size of the container, except for solid oral dosage forms, without a change in the approved container and closure system;

(9) An extension of the expiration date of the animal drug product based on data obtained under a new or revised stability testing protocol that has not been approved in the application;

(10) A change in the procedure for reprocessing a batch of an animal drug product that fails to meet specifications; or

(11) Any change in labeling not covered by proposed § 514.70 (c)(2) or (d).

FDA believes that these changes needing prior approval are of a type that are more likely than others to affect the safety or effectiveness of an animal drug.

b. *Supplement for changes that may be made before FDA approval (§ 514.70(c)).* Although most changes in labeling would require the applicant to submit a supplement and obtain FDA approval before making a change, the following changes in labeling, which would make available important new information about the safe use of an animal drug product, could be made without prior approval of FDA if the applicant submits a supplement when the change is made: A change that adds or strengthens a contraindication, warning, precaution, or statement about an adverse reaction or overdosage; a change in any other instruction about dosage or administration that is intended to improve the safe use of the product; or a change that would delete a false, misleading, or unsupported indication for use.

FDA is proposing that an applicant also be permitted to make a change of the kinds listed below without FDA approval before the change is made if the applicant submits a supplement when making the change: Adding a new specification, adding a test method, or changing a method or control to provide increased assurance that the animal drug will meet the requirements of identity, strength, quality, and purity that the animal drug purports or is represented to possess. Although a change identified above may present some risk with respect to the safety and effectiveness of the product, FDA believes that any such risk is minimal, because the animal drug product would still be required to comply with each of the in-process and final specifications already approved in the original application. In addition, FDA promptly reviews supplements containing these kinds of changes.

Proposed § 514.70(c)(3) would permit an applicant to use a different facility or establishment to manufacture an animal drug substance, except in the three circumstances described above, if the manufacturer submits a supplement when making the change. This proposal would give an applicant greater flexibility in purchasing a bulk animal drug substance on the domestic and international markets.

FDA is proposing to retain the requirement for prior approval of a change in the supplier of an animal drug substance that will be administered to animals as a biomass product. A biomass product obtained from two different manufacturers may have similar characteristics insofar as the animal drug substance is concerned, but the toxicologic profiles of the total biomass may be significantly different due to the media, fermentation procedure, or strain of microorganism used. Thus, the agency subjects biomass products to special review.

c. *Changes that may be described in a drug experience report (§ 514.70(d)).* A change of the following types would be permitted in the conditions of approval of a new animal drug product without the submission or approval of a supplement, provided the change is fully described in reports submitted under proposed §§ 514.80 through 514.82.

(1) Changes in the specifications or methods for active and inactive ingredients to bring them into compliance with current specifications or methods in the official compendium.

(2) A different container size for solid oral dosage forms, (e.g., tablets or capsules) where container and closure are of the same materials as those provided for in the approved application.

(3) Change in equipment that does not alter the method of manufacture of a new animal drug.

(4) Change from one batch size to another without any change in manufacturing procedure unless the change involves a greater than ten-fold increase in batch size.

(5) Change to more stringent specifications without altering the method described in the approved application.

(6) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(7) Initiation of a product identification coding system.

(8) Change from paper labels to direct printing on glass or other kinds of immediate containers without a change in text.

(9) Extension of the current expiration date based on full shelf-life data obtained using a stability protocol approved in the application.

(10) Addition of precautionary statements, explanations, and clarifications to manufacturing and control procedures.

(11) Minor editorial or similar minor label changes, such as changes in the ink colors of the label, the addition of an NADA number and an FDA approval statement, changes in the placement of the text on the label as long as the FDA label guidelines are followed, the revision or updating of a company logo or label design, and the correction of typographical errors.

(12) Changes in the marking of solid oral dosage forms which do not result in any changes in the labeling or approved specifications for the drug product.

(13) Reduction or elimination of manufacturing overages for drug and nondrug ingredients.

(14) Changes in suppliers of inactive ingredients, containers, and closures provided the product of the new suppliers are shown to meet approved criteria.

(15) Changes in in-plant coding and control number systems; e.g., material and product identification codes, lot numbering systems of raw materials, specification and method codes.

(16) Changes in outer packaging material, such as carton shape, color, or style of printing which do not decrease the degree of protection of the drug, modify approved labeling text, or decrease legibility of print.

(17) Changes in or replacement of noncompendial specifications and methods for ingredients, except those used for the determination of identity, potency, purity, sterility, and safety of the ingredients.

d. *Changes permitted pending finalization of the National Academy of Sciences/National Research Council (NAS/NRC) review (§ 514.70(e)).* This paragraph is the same as current § 514.8(g) except for a minor editorial revision for the purpose of clarification.

The agency would continue to permit certain types of changes prior to approval of a supplement to an NADA that became effective before October 10, 1962, pending completion of the review of effectiveness of the animal drug by the NAS/NRC and a determination of whether there are grounds for refusing, suspending, or withdrawing approval. The applicant must have written authorization from FDA prior to implementing such a change in advance of approval. The type of changes permitted by FDA are those that do not adversely affect, but may enhance the safety, effectiveness, quality, or stability of the product.

15. Procedure for Submission of a Supplement to an Approved Application (Section 514.71)

The agency proposes to codify its policy for the submission of a supplement to an approved application. All procedures and actions that apply to an application under proposed § 514.50 and a minor use application under § 514.58 also apply to a supplement, except that the information required in a supplement is limited to that needed to support a change.

16. Change in Ownership of an Application (Section 514.72)

The agency proposes to codify its policy on a change in ownership of an approved application. Under the proposal, when ownership is transferred, the former owner of the application would provide the agency written notification of the change. The new owner must also provide written notification of the change and, in addition, a signed application form and a letter or other document stating the date that the change of ownership is effective. The new owner must make a commitment to comply with all agreements, promises, and conditions made by the former owner contained in the application. The new owner must also confirm that it has a complete copy of the application or ask FDA to provide one.

A change in ownership of an application, including a change in labeling to reflect a new brand name or the name of the new manufacturer, packer, or distributor, would not require FDA approval if each of the conditions in proposed § 514.72 is met. FDA approval would be required, however, if the new owner makes a change in the application that would require a supplement under proposed § 514.70 (b) or (c). A "regulation" reflecting the change of ownership would be published in the **Federal Register** under section 512(i) of the act.

Withdrawal of a request to transfer ownership of an application must be made in writing to FDA and must have the concurrence of all parties, as must a request, following FDA's receipt of the information and documents required to effect a change in ownership, that ownership not be transferred.

17. Supplemental Application for an Animal Feed Bearing or Containing a New Animal Drug (Section 514.75)

As proposed, this section provides that the applicant is to complete only part of the MFA and specifically address the changes being proposed. Section 514.75 would thus reduce paperwork while maintaining the integrity of the application.

Also, FDA is providing procedures for the establishment of list (facilities) master files (LMF) for firms with multiple feed manufacturing facilities (multimill firms) that have more than one approved medicated feed application. The LMF procedures will reduce the amount of paper work needed to make changes in mill lists, allowing for a single submission to make simultaneous changes in mill lists for all of a firm's MFA's. In addition, FDA is proposing procedures for deleting a mill from mill lists by the submission of a letter, rather than a Form FDA 1900.

18. Maintenance of Copies of Approved Applications for Animal Feed Bearing or Containing New Animal Drugs (Section 514.83)

This section would be recodified unchanged from current § 510.305.

19. Waivers (Section 514.90)

The agency proposes to add a section under which an applicant may obtain a waiver of a nonstatutory requirement for the submission of information in an application. An applicant may submit a request for such a waiver with supporting information in an original application, a supplemental application, or an amendment to either an original or supplemental application. The request for a waiver must justify why the requirement is unnecessary or cannot be achieved in a particular case, describe an alternative submission that satisfies the purpose of the requirement, or provide other information justifying a waiver.

FDA may grant a waiver of a nonstatutory requirement if the agency finds that the applicant's compliance with a requirement is unnecessary, the applicant makes an alternative submission that satisfies the

requirement, or the applicant otherwise justifies a waiver. This waiver provision is intended to give applicants flexibility to seek alternative ways of complying with the statutory standards for new animal drug approval. Clearly, however, FDA is unable to waive statutory requirements.

C. FDA Actions on Applications

1. Time Frames for Reviewing an Application (Section 514.100)

FDA is proposing to revise its regulations regarding agency actions in filing, reviewing, and approving or refusing to approve an application. Under section 512(c) of the act (21 U.S.C. 360b(c)), within 180 days after an application for a new animal drug is filed, FDA must either approve the application or give the applicant notice of an opportunity for a hearing on whether the application is approvable, unless FDA and the applicant agree to an extension. The agency proposes to revise its regulations to specify, in accordance with the statute, how long FDA may take to review an application, when FDA would file an application, and the circumstances in which the review period could be extended.

The key to the proposal is a provision under which FDA would be required to send to an applicant an action letter (that is, an "approval" letter, an "approvable" letter, or a "not approvable" letter) within 180 days of FDA's receipt of the application. Although FDA could extend this time period if an amendment is submitted to the application, any extension would be for only the additional period of time necessary for review of the amendment. Thus, under this proposal, applicants would be assured of a response from the agency within a reasonable period of time on whether the application is approvable.

2. Filing an Application (Section 514.101)

The proposal contains several technical features regarding the "filing" of an application and the issuance of a notice of opportunity for a hearing. Under the proposal, FDA would determine within 60 days after receipt of the application whether it is acceptable for filing, and the applicant would receive notification at the 60-day point stating whether the application is indeed "filed." This proposed provision would give the applicant earlier feedback on whether the application is suitable for filing, but it would not affect FDA's commitment to issue an action letter to the applicant within 180 days of receipt of the application.

FDA's proposed time frames for actions from date of receipt and from date of filing are shown in a table at the end of this preamble section.

The proposed date for "filing" an application would be an important change from current practice. Currently, FDA has 30 days after receipt of an application to determine its acceptability for filing. Because an application consisting of numerous volumes is physically difficult to handle, very often more than 30 days pass after receipt before review of an application is initiated. FDA finds that it cannot always determine within the 30-day period now specified whether an application is suitable for filing. By contrast, the agency believes that the 60-day period proposed is a reasonable period of time during which FDA can make a threshold determination on whether an application is acceptable for filing. That period would give agency reviewers an opportunity to perform a cursory review of each application and to prepare and issue a "Refusal to File" letter in cases where an application is obviously incomplete, or where it may not be filed because of other regulatory provisions.

The proposal would modify the current mechanism for "filing over protest." Under the current system, upon the issuance of a "Refusal to File" letter, the applicant may request that the application be filed over protest. This request results in an immediate "filing over protest," and obligates the agency to conduct a complete review of the application. The proposal provides that, if FDA notifies an applicant within 60 days of receipt of the application that the application is not suitable for filing, the applicant would be permitted to request in writing, within 30 days of the date of FDA's notification, an informal conference to discuss the inadequacies in the application. If following the informal conference the applicant requested that FDA file the application, FDA would file the application over protest as provided by proposed § 514.101(b), notify the applicant in writing, and review it as filed. If the application were filed over protest, the date of filing would be 60 days after the date the applicant requested the informal conference.

FDA is also proposing to reduce to 60 days the time period between the issuance of a "not approvable" letter and the issuance of a notice of opportunity for a hearing, including a 10-day period during which the applicant may notify CVM if the appplicant wants CVM to issue such a notice. This proposed revision would expedite administrative hearing procedures in those instances where an applicant wishes to invoke them.

3. Two Overlapping 180-Day Time Periods (Section 514.101(b))

FDA is proposing to establish two overlapping 180-day time periods. The agency recognizes that some persons may initially find this scheme confusing, but believes that the proposal meets both the pragmatic concerns of applicants and the requirements of the statute. From a pragmatic standpoint, what applicants care about most is how long FDA will take from receipt of the application until reaching an institutional decision on whether the application is approvable. This is the 180-day clock described above at the beginning of this preamble section. The statute (section 512(c) of the act), however, speaks in terms of issuing a "notice of opportunity for a hearing" rather than an "action letter," and it is the time between the filing date and the date of issuance of a notice of opportunity for a hearing which, by statute, must be within 180 days. The proposal would also satisfy this legal requirement.

The two overlapping 180-day time periods are illustrated in the following table:

Actions	Days from submission (FDA's operating time frame)	Days from filing (statutory time frame)
1. FDA receipt of application	0	
2. Filing	60	0
3. Action letter issues	180	120
4. Applicant may request issuance of a notice of opportunity for a hearing	190	130
5. Notice of opportunity for a hearing issues	240	180

Because a notice of opportunity for a hearing is issued for relatively few applications, FDA believes that the proposed operating time frame of 180 days "from receipt to action letter" is the most important time period to applicants.

4. Communications Between FDA and an Applicant (Section 514.102)

FDA believes that increasing and improving communications between the agency and applicants can do much to facilitate review of applications. Frank and open discussions involving

individuals who develop applications and FDA officials and personnel who review those applications can enhance the application of good science to the animal drug approval process. FDA encourages such communications wherever feasible, both before an application is submitted and while it is under review.

a. *Communications before submission of an application.* In the agency's experience, a presubmission conference, where the applicant meets with the reviewing team to discuss the best way to present the information in the application, is exceedingly helpful in speeding up FDA's subsequent review of an application. A significant source of delay in FDA's review of applications occurs when reviewers need to ask the applicant to analyze or present the data in the application differently. A presubmission conference may help avoid such delay. FDA strongly encourages applicants to initiate a presubmission conference, especially if the applicant is relatively inexperienced in new animal drug development. However, FDA is not proposing to require that a presubmission conference be held because such a conference is not always necessary. FDA requests that all conferences and meetings be scheduled in advance.

b. *Communications during review of an application.* FDA believes that more communication between the agency and an applicant during the review of an application would be mutually advantageous. Such communications permit an applicant to monitor the progress of the review and to learn of deficiencies as soon as possible, so that the applicant can promptly correct any deficiencies. FDA is taking the following steps to encourage such communications.

First, FDA would determine within 60 days of receipt of an application if the application is acceptable for filing. Under this proposal, every applicant would receive from the agency within 60 days from the submission date a letter concerning the suitability of the application for filing. If the application is not filed, FDA suggests that the applicant request an informal conference with reviewing officials and personnel.

Second, the agency is directing its reviewing staff to inform applicants of easily correctable deficiencies as they are discovered, in order to allow applicants to submit amendments to correct minor deficiencies within the 180-day review period.

Third, FDA may schedule a meeting during the review to inform the applicant of the general progress and status of the application and to discuss important deficiencies that have been identified. The agency encourages such a meeting, which may be held by telephone, if mutually agreeable. Unless it is extremely urgent (e.g., to discuss important new safety information), FDA strongly requests that the applicant or the applicant's representative not make unannounced or unscheduled visits with FDA personnel performing reviews. Such visits can be scheduled on relatively short notice.

5. Dispute Resolution (Section 514.103)

During review of an application, agency reviewers or division management may, under procedures described in proposed § 514.102(a), communicate with the applicant orally or in writing about what they believe are scientific deficiencies in the application. Reviewers may ask for additional information, data, or changes in the application to facilitate their review. In some cases, an applicant may question the need for an additional submission or a change in an application, or may disagree with FDA's request. An applicant may seek to modify or reverse an agency request through informal meetings with persons in reviewing divisions or through telephone conversations or letters. FDA intends to continue its policy of allowing applicants to informally negotiate such differences with the agency.

The agency recognizes, however, that a dispute between an applicant and a reviewing division regarding scientific or veterinary medical issues may not always be resolved after one or more meetings described in proposed § 514.102(c). If the applicant and the reviewing division conclude that an impasse exists, proposed § 514.103(c) would permit the applicant to appeal the division's decision.

Since 1981, CVM has used an appeals procedure for resolving disputes. The procedure has worked well. For this reason, the agency would retain it in proposed § 514.103(c)(2). CVM's appeal procedure is detailed in its Policy and Procedures Manual and is available to the public under FDA's Freedom of Information regulations.

6. Drug With Potential for Abuse (Section 514.104)

FDA has followed the practice of notifying the Drug Enforcement Administration if an application is submitted for a new animal drug that appears to have the potential for abuse. In proposed § 514.104, FDA would codify that practice. The proposal is consistent with the NDA Rewrite.

7. Action Letter

Under the proposal, after FDA completes its substantive review of an application, the agency would send to the applicant one of three action letters: An "approval" letter, an "approvable" letter, or a "not approvable" letter. (The proposed "approvable" letter and "not approvable" letter are both encompassed by CVM's current "incomplete" letter.)

a. *"Approval" letter (§ 514.105).* If FDA finds that none of the grounds in the statute for refusing to approve an application applies, the agency would approve the application and send the applicant an "approval" letter (§ 514.105). Only an approval letter would permit the marketing of a new animal drug. The proposed procedure for issuance of an "approval" letter is the same as current practice, as qualified below. FDA is proposing an important change. If an application contains minor deficiencies, such as deficiencies in the product's draft labeling, FDA is proposing to approve the application before the final corrections are submitted, with the condition that the deficiencies will be corrected before the product is marketed. In such a case, the "approval" letter would describe the specific conditions needing correction before any marketing of the product.

The "approval" letter to an applicant would take one of two forms, depending upon the animal drug product. First, if the animal drug product is a pharmaceutical dosage form (tablet, capsule, powder, or solution) or a Category I Type A medicated article that is not to be mixed with a Category II Type A medicated article, FDA is proposing that the "approval" letter state that the application is approved upon the date of the letter. Second, if the animal drug product is a Category II Type A medicated article (or a Category I that is to be mixed with a Category II), FDA is proposing that the "approval" letter state that the approval is effective upon the date of its publication in the **Federal Register** of the requisite "regulation" under section 512(i). In each of the cases above, marketing may not be initiated until copies of the final printed labeling have been submitted to FDA.

The date of approval of a Category II Type A medicated article (or a Category I that is to be mixed with a Category II) is the date of publication in the **Federal Register** of a "regulation" reflecting the approval because of the statutory provisions regulating the manufacture of Type B and Type C medicated feeds. Section 512(m) of the act requires that

an application to manufacture an animal feed bearing or containing a new animal drug contain, among other things, a reference to the regulations providing for such use. Thus, medicated feeds cannot be prepared unless a "regulation" has been published providing for use of the Category II Type A medicated article.

b. *"Approvable" letter (§ 514.110) and "not approvable" letter (§ 514.120).* If an application contains deficiencies, FDA is proposing that it would issue to the applicant either an "approvable" letter (§ 514.110) or a "not approvable" letter (§ 514.120). An "approvable" letter means the agency believes that important, but easily resolved, deficiencies exist in the application, and that FDA will approve it if the applicant submits specific additional information or material identified in the letter or agrees to other specific conditions. A "not approvable" letter reflects the agency's conclusion that major deficiencies exist in the application, or that information in the application is unable to support approval of it.

8. Applicant's Response to an Action Letter

Under the proposal, an applicant would be required to respond to either an "approvable" or a "not approvable" letter within 60 days, unless FDA and the applicant both agree to an extension of the response time. The applicant's response would (1) withdraw the application, (2) amend the application or notify FDA of its intent to file an amendment, or (3) ask the agency to provide the applicant a notice of opportunity for a hearing on a proposal to refuse approval of the application under section 512(d) of the act or § 514.125. FDA would deem an applicant's failure to respond within 60 days to be a withdrawal of the application by the applicant. The withdrawal of the application would be without prejudice to refiling.

If FDA sends the applicant an "approvable" letter and the applicant files an amendment or notice of intent to file an amendment, FDA would review the amendment and take appropriate action within 45 days of its receipt. If FDA sends the applicant a "not approvable" letter requiring the applicant to attempt to resolve major deficiencies in the application by amendment, FDA would extend the review period for the time needed to review the amendment.

8a. Categories of Supplemental Applications (21 CFR 514.106)

As discussed earlier in this preamble, in reference to supplemental applications (§ 514.70), current § 514.106 *Approval of supplemental applications* is being amended to read § 514.106 *Categories of supplemental applications,* and is included for the sake of completeness rather than for comment.

9. Foreign Data (Section 514.107)

The agency is proposing requirements regarding the acceptance of foreign data in support of the safety and effectiveness of a new animal drug. The proposed requirements for most studies are the same as those required of similar studies conducted in the United States, but FDA is proposing that foreign clinical data must meet certain additional criteria in order to be accepted in support of the safety and effectiveness of a new animal drug. The foreign data must reflect appropriate animal treatment in the United States; the studies must have been conducted by qualified and recognized clinical investigators; and the data must be considered valid without the need for an FDA on-site inspection, or, if FDA determines that such an inspection is necessary, FDA can validate the data through an on-site inspection or by other appropriate means.

10. Refusal to Approve an Application (Section 514.125)

The agency proposes to retain the grounds for refusing to approve an application in the current regulations, but to amend the regulations to provide that CVM will prepare and issue a notice of opportunity for a hearing on a proposed refusal only if each of the following three conditions is met:

(1) CVM sends the applicant an "approvable" letter or a "not approvable" letter;

(2) The applicant, within 60 days of the date of the letter, asks CVM to issue a notice of opportunity for a hearing; and

(3) CVM concludes that grounds exist under section 512(d) of the act or § 514.125 for refusing approval of the application.

FDA is also proposing to add the following grounds for refusing to approve an application to those in the current regulations:

(1) The applicant refuses to correct a deficiency for which the agency may refuse to file an application (this ground might apply to an application filed over protest);

(2) The animal drug product will be manufactured processed in an establishment that is not registered or exempt from registration or records relevant to the application;

(3) The applicant's facilities do not comply with the agency's current good manufacturing practice regulations;

(4) The animal drug product's labeling does not comply with the agency's labeling regulations (other than minor deviations that are easily correctable); and

(5) The applicant or contract research organization does not retain reserve samples of the drug products used to conduct bioavailability or bioequivalence studies or release those samples to FDA when so requested (this proposed requirement conforms to that of the interim rule published in the **Federal Register** of November 8, 1990 (55 FR 47034)).

A notice of opportunity for a hearing on a proposed refusal to approve an application would generally provide, as such notices now do, a detailed description and analysis of the specific facts resulting in CVM's proposed refusal, and would refer to specific requirements in the act and regulations under which CVM proposed to refuse approval of the application. An applicant would have, as it does now, 30 days to respond to such a notice. If the applicant requests a hearing, the agency would issue a notice granting or denying a hearing within 90 days of the expiration of the 30-day period.

11. Adequate and Well-Controlled Studies (Section 514.126)

The agency is proposing to retain with minor editorial revisions the regulations in current § 514.111(a)(5) describing the criteria for an adequate and well-controlled study, except that FDA is proposing to establish the requirements in a separate section of the regulations (§ 514.126).

12. Incomplete Application for an Animal Feed Bearing or Containing a New Animal Drug (Section 514.129)

The agency is proposing that an application found incomplete due to deficiencies or inaccuracies in the information required in § 514.51 be considered withdrawn without prejudice to future filing, unless within 30 days of the date of issuance of the letter citing the deficiencies or inaccuracies the applicant requests a notice of opportunity for a hearing.

13. Withdrawal of Approval of an Application (Section 514.150)

The agency is proposing to retain the grounds for withdrawing approval of an application in the current regulations, but is proposing two new substantive provisions. Proposed § 514.150(d) would permit an applicant to voluntarily

request withdrawal after CVM has notified the applicant that grounds for withdrawal may exist. The proposal would permit CVM to notify an applicant if CVM believes a potential problem associated with the new animal drug product is sufficiently serious to warrant the products' removal from the market. CVM may ask the applicant to voluntarily remove the product from the market, waive the notice and opportunity for a hearing, and permit CVM to withdraw approval of the application. If the applicant complied with CVM's request, CVM would not make the detailed finding it would otherwise be obligated to make when withdrawing approval. CVM would, however, when publishing a notice of a voluntary withdrawal of approval of an application, give a brief summary of the reasons for the voluntary withdrawal.

Proposed § 514.150(b)(3)(iii) would provide for the issuance of a notice of opportunity for a hearing on a proposal to withdraw an application approved pursuant to section 512(c) of the act if CVM finds that the applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

a. *Section 512(e)(1)(B) of the act—new evidence.* As discussed in two notices of opportunity for a hearing proposing to withdraw approval of several NADA's, new animal drugs are not shown to be safe within the meaning of section 512(e)(1)(B) of the act when new evidence provides a reasonable basis from which serious questions about the ultimate safety of the drug and the residues that may result from its use may be inferred, when new evidence shows that the drug is no longer shown to be safe by adequate tests by all methods reasonably applicable, and when new evidence shows that the labeled directions for use have not been followed in practice and are not likely to be followed in the future. See "Dimetridazole; Opportunity for Hearing" (51 FR 45244, December 17, 1986), and "Chloramphenicol Oral Solution; Opportunity for Hearing" (50 FR 27059, July 1, 1985).

Section 512(e)(1)(B) of the act is part of the Animal Drug Amendments of 1968, which consolidated into one section (section 512 of the act), the various provisions of the act that related to "new drugs" intended for use in animals. Prior to 1968, the definition of "new drug" in section 201(p) of the act (21 U.S.C. 321(p)), did not distinguish between drugs intended for use in man or other animals, and the premarket clearance provisions of section 505 of the act applied to new drugs intended for both man and other animals. Under section 505(e)(2) of the act, which was added to the statute in 1962, FDA must withdraw approval of a new drug application (NDA) if, after due notice and opportunity for hearing to the applicant, the agency finds that "new evidence" shows that the drug that is the subject of the application is not shown to be safe for use under the conditions of use upon the basis of which the NDA was approved.

b. *Section 512(e)(1)(B) of the act—safety.* Section 505(e)(2) was intended to "[c]larify and expand the authority to withdraw approval on safety grounds so that the manufacturer would continue to have the burden of showing that the drug is safe, as he has on the original submission." See 108 Cong. Rec. 17366 (1962) (statement of Senator Eastland, a sponsor of S. Doc. 1552, which was the forerunner of section 505(e)(2) of the act). See also 108 Cong. Rec. 21080 (1962). Under section 512(e)(1)(B) of the act, which is the new animal drug analog of section 505(e)(2) of the act, the manufacturer also continues to have the burden of showing safety. See S. Rept. No. 136, 90th Cong., 2d Sess. 3 (1968) ("[t]he enactment of [the Animal Drug Amendments of 1968] would in no way weaken the authority of [FDA] with respect to the regulation of new animal drugs").

c. *Section 512(d)(1)(A) of the act—methods to show safety.* Section 512(d)(1)(A) of the act requires FDA to refuse to approve an NADA if the agency finds that:

> * * * the investigations, reports of which are required to be submitted to the [FDA] pursuant to subsection (b), [section 512(b)], do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof * * *.

The analog of section 512(d)(1)(A) of the act is section 512(e)(1)(B) of the act, which requires withdrawal of approval of an NADA where:

> * * * tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the [FDA] when the application was approved, shows that such drug is not shown to be safe * * *.

FDA can satisfy its burden under section 512(e)(1)(B) of the act by citing (1) progress in scientific standards (new evidence) such that new tests are needed for a safety evaluation under current scientific standards, and (2) a failure by the applicant to do such tests. Section 512(e)(1)(B) of the act is not as explicit as section 512(d)(1)(A) of the act in imposing on the applicant the duty to conduct tests and submit the results. But the general philosophy of section 512 of the act (as of sections 409, 505, and 706 of the act (21 U.S.C. 348, 355, and 376)) is that testing shall be the responsibility of the firm, and not the agency. That philosophy is explicitly reflected in section 512 (b)(1)(A) and (d)(1)(A) of the act. There is no reason to interpret section 512(e)(1)(B) of the act differently.

Section 512(d)(1)(A) of the act uses the phrase "adequate tests," but section 512(e)(1)(B) of the act does not. Nevertheless, it would be absurd to interpret "tests" in section 512(e)(1)(B) of the act as including inadequate tests.

Therefore, it is appropriate to read "tests" in section 512(e)(1)(B) of the act as "adequate tests." It is also appropriate to read the general "new evidence" provision of section 512(e)(1)(B) of the act as incorporating the standard of "adequate tests by all methods reasonably applicable," which appears in section 512(d)(1)(A) of the act. Thus, if new evidence of scientific progress shows that the data supporting an NADA no longer constitute adequate tests by all methods reasonably applicable to a determination of safety, that new evidence warrants withdrawal under section 512(e)(1)(B). *Cf. United States* v. *Western Serum Co., Inc.*, 666 F.2d 335 (9th Cir. 1982) (absent current general recognition of the safety of an animal drug, that drug is a new animal drug and must have an approved NADA).

d. *Section 512(a)(1)(B) of the act—labeling and conditions of use.* Section 512(a)(1)(B) of the act provides that a new animal drug is unsafe unless the drug, its labeling, and its use conform to that provided for in the approved NADA for the drug. Section 512(d)(2)(D) of the act provides that in determining whether a drug is safe for use under the conditions prescribed, recommended, or suggested in the labeling, the agency is to consider, among other factors, whether those conditions of use are reasonably certain to be followed in practice. Accordingly, where labeled conditions including indications for use of an approved new animal drug have not been followed, or are not reasonably certain to be followed in practice, the animal drug is not shown to be safe for

use and therefore its approval is subject to withdrawal under section 512(e)(1)(B) of the act. Furthermore, the use or intended use of an approved new animal drug in a manner that is inconsistent with the conditions of its approval causes the animal drug to be unsafe and thereby adulterated under sections 501(a)(5) and 512(a)(1) (A) and (B) of the act. The approval of such an adulterated drug is also subject to withdrawal under section 512(e)(1)(B) of the act.

14. Notice of Withdrawal of Approval of an Application for a New Animal Drug (Section 514.152)

The agency proposes to codify its policy to provide public notice of the withdrawal of approval of an application for a new animal drug. If FDA withdraws approval of an application for a new animal drug, FDA will publish a notice in the Federal Register announcing the withdrawal and a final rule removing the regulations reflecting the approval. An application providing for the manufacture of an animal feed bearing or containing a new animal drug and approved pursuant to section 512(m)(2) of the act will be deemed to be withdrawn upon publication of the final rule removing the corresponding regulation.

15. Approval or Reinstatement of an Application for Which Approval was Refused, Suspended, or Withdrawn (Section 514.160)

FDA is proposing to make only editorial revisions in current § 514.120 and also establish a new section number for these requirements (proposed § 514.160).

16. Adulteration and Misbranding of an Approved Animal Drug (Section 514.170).

The agency proposes to add a new section in the regulations to clarify the relationship between the premarket approval requirements of the act and its adulteration and misbranding provisions. This new section would provide the same regulatory interpretation for new animal drugs as was established for new drugs under the NDA Rewrite.

D. Hearing Procedures for New Animal Drugs (Sections 514.200, 514.201, 514.235)

The agency proposes to make substantive changes of the regulations in §§ 514.200, 514.201, and 514.235 describing notices of opportunity for hearing on proposals to refuse to approve applications or to withdraw approval of approved applications, notices of participation and requests for hearing, notices and orders granting and denying hearings with respect to new animal drugs, procedures for hearings, and judicial review. The proposed changes in the regulations clarify the responsibility of both FDA and applicants with respect to hearings. The changes would set forth in greater detail the process and content of a response to a notice of opportunity for a hearing. This additional detail should aid applicants in preparing appropriate and adequate responses to such notices.

The applicant would have 30 days from the date of publication of the notice to file with FDA's Dockets Management Branch a notice of participation and a request for a hearing. Within 60 days from the date of the notice of opportunity for a hearing, the applicant would have to file with the Dockets Management Branch data, information, and analysis relied on to justify the request for a hearing.

The supporting information to be submitted by the applicant would include studies, protocols and raw data, and factual analysis of all information relied on to justify the request for a hearing. The proposed rule specifies a format for submission of data to support a request for a hearing. The proposed rule also contains provisions regarding separation of functions within the agency and administrative summary judgment.

These proposed changes are consistent with those promulgated under the NDA Rewrite, except that the proposed rule, unlike the NDA Rewrite, does not include provisions regarding contentions that an animal drug product is not subject to the new animal drug requirements of the act. If an animal drug product is generally recognized as safe and effective within the meaning of section 201(w) of the act (21 U.S.C. 321(w)), or if it is "grandfathered" under the exemption for products marketed before June 25, 1938, contained in section 201(w) of the act, or under section 108(b)(3) of the Animal Drug Amendments of 1968, it may be exempt from some or all of the new animal drug provisions of the act. Contentions that an animal drug product is not subject to the new animal drug requirements of the act have rarely been made. For this reason, FDA decided not to burden the proposal with provisions governing such contentions. If the need arises, CVM will specify in a notice of opportunity for a hearing proposing to refuse or withdraw approval of an application for a new animal drug the data, information, and factual records that are necessary and appropriate to support the contention(s) in question, relying on the act and its legislative history and purpose, the decided cases, and any applicable regulations.

E. Subpart E [Reserved]

In order to retain a format that parallels that of 21 CFR part 314, subpart E in 21 CFR part 514 is reserved because there no longer are provisions for the certification of antibiotic new animal drugs.

F. Miscellaneous Provisions

1. Imports and Exports (Section 514.410).

Section 301 of the act (21 U.S.C. 331) prohibits interstate commerce in unapproved new animal drugs. The definition of such commerce in section 201(b) of the act (21 U.S.C. 321(b)) effectively includes commerce in imports and exports. In addition, section 801(d) of the act specifically prohibits the exportation of a new animal drug that is unsafe within the meaning of section 512(b) of the act (e.g., is not the subject of an approved NADA or an exemption granted for an investigational new animal drug (INAD)). Under section 802 of the act, however, such a new animal drug may be exported if it is the subject of an approved export application. Thus, a new animal drug product may be imported only if it is the subject of an approved NADA or of a valid INAD, and may be exported only if it is the subject of an approved NADA, a valid INAD, or an export application approved under section 802 of the act. In addition, a bulk animal drug substance may be imported if it complies with 21 CFR 201.122.

FDA is proposing to codify the agency's current policy on imports and exports of a new animal drug, with two changes. The first proposed change would permit a supplier of a bulk animal drug substance used in an approved new animal drug product to export the bulk animal drug substance even if the animal drug substance manufacturer does not hold an approved application for an animal drug product containing the substance. The agency is proposing this action to make the animal drug regulations consistent with those for human drugs and to facilitate commerce in bulk animal drug substances. Because FDA generally does not approve applications for new animal drug substances, it would consider the approval of the application for a new animal drug product, which contains detailed information about the new animal drug substance, to cover the export of that substance. The export shipment would be required to meet the same specifications the new animal drug substance must meet for use in the

approved new animal drug product and to include a copy of the labeling for the product.

The second proposed change in FDA's current policy on imports and exports is the acknowledgement in § 514.410(b)(iii) of the right to export an unapproved new animal drug product under section 802 of the act (the Drug Export Amendments Act of 1986). The agency is currently developing policies and procedures to implement section 802. FDA intends to make these policies and procedures available to the public for comment in the future.

2. Drug Master File (Section 514.420)

The agency proposes to amend substantially the regulations to provide for drug master files in order that the regulations reflect current practice. A drug master file is a body of information that a person (a holder of a drug master file) submits to FDA. The existence of a drug master file permits its holder to incorporate the information in an INAD, an NADA, an ANADA, or another submission to the agency without having to resubmit individual copies of the information. In addition, the holder may authorize other persons to rely upon information to support their submissions to FDA without the holder or the agency disclosing to the other persons information in the master file that may be a trade secret. The proposed regulations describe a master file and clarify that FDA reviews the content of a master file only in the context of its review of an application.

The proposal lists five examples of a drug master file that the agency accepts. The drug master file holder is requested to review the drug master file annually and notify CVM in order to keep the file up to date. The proposed regulations specify that each incorporation from a drug master file is required to describe the incorporated material by name, reference number, volume, and page number. The regulations would require the holder to (1) submit two copies of the drug master file, (2) maintain a list in the master file of each person authorized to incorporate information in the file and identify the information the person is authorized to incorporate, and (3) notify, in writing, each person authorized to refer to information in the file each time the file holder makes a change in the information upon which that person relies. Proposed § 514.420 would be consistent with § 314.420 established under the NDA Rewrite.

3. Public Master File (Section 514.421)

The agency is proposing a new section to provide for public master files. Information from such files may become available for incorporation into an INAD, an NADA, or an ANADA.

4. Availability for Public Disclosure of Data and Information in an Application (Section 514.430)

The agency is proposing to redesignate the regulations regarding the availability for public disclosure of data and information in an application, and to make minor changes in those regulations, primarily concerning the timing of disclosure.

5. Addresses (Section 514.440)

FDA proposes a new section that would designate various agency offices to which applications, filings, and other correspondence should be sent.

6. Guidelines (Section 514.445)

The agency is also proposing a new section that reflects the agency's use of guidelines to help persons comply with the regulations. Although the proposed rule would establish general provisions for the kind, quantity, and presentation of data needed to obtain marketing approval of a new animal drug, FDA is proposing to give applicants a great deal of flexibility in putting together an application. Such guidelines do not bind FDA nor do they in any way create or confer any rights, privileges, or benefits for any person. In the preamble to any final rule, FDA will include a list of applicable guidelines. The preamble will also state how a person can obtain a copy of each guideline.

IV. Animal Feeds

At the time any final rule based on this proposal is published, the agency will revise and redesignate certain portions of the regulations in 21 CFR part 510 into part 514 and revise and redesignate certain others in part 514. Those regulations concern the approval of new animal drugs for use in animal feeds. Specifically, § 510.305 will be revised and redesignated as § 514.83; § 514.2 as § 514.51; § 514.9 as § 514.75; and § 514.112 as § 514.129. The major provisions of these regulations were substantially revised in a final rule that was published in the Federal Register of March 3, 1986 (51 FR 7382).

V. Records and Reports

In a proposed rule published elsewhere in this issue of the Federal Register, the agency is proposing to amend the regulations for reporting and recordkeeping currently at 21 CFR 510.300 to 510.302 by incorporating certain portions of the existing requirements into proposed 21 CFR 514.80 to 514.82.

VI. Conforming Amendments of the Proposed Rule

These proposed regulations, if promulgated, will necessitate changes in various regulations in parts 10, 12, 16, 20, 500, 510, 511, and 514.

A. Part 510, Subpart C—Exportation of New Animal Drugs

In part 510, FDA proposes to remove the heading "Subpart C—Exportation of New Animal Drugs", to incorporate the material in § 510.200 into § 514.410, and to substantially revise and update the section and its heading as noted above.

B. Part 511, New Animal Drugs for Investigational Use

In part 511, FDA proposes to establish a new § 511.2 to describe the public information aspects of investigational new animal drug applications formerly described in § 514.12 *Confidentiality of data and information in an investigational new animal drug notice.*

C. Other Conforming Amendments To Reorganize the Regulations

In parts 10, 12, 16, 20, and 500, conforming amendments have been proposed to reflect the proposed reorganization of part 514.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

FDA has examined the economic consequences of these proposed regulations governing new animal drugs in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). The requisite threshold assessment required by these provisions was completed in 1987.

The agency concludes that the proposed rule, if promulgated, will improve the efficiency of the agency's NADA review process without compromising the high level of public health protection that process now provides. The reviewing efficiencies will benefit both the public and applicants by facilitating earlier availability and marketing of safe and effective new animal drugs and expedite withdrawal of approval of new animal drugs that are no longer shown to be safe and effective.

Although not every impact can be quantified, the agency estimates, based

on the 1987 threshold assessment, that the proposed changes in the approval process may provide a modest net savings to animal drug manufacturers—perhaps as much as $1 million per year. An estimated $1.7 million per year in annual savings may be achieved through earlier receipts of sales revenues due to quicker approvals, decreases in the number of supplements sent to the agency, and a reduction in the number of NADA copies submitted. A significant portion of those savings is based on the assumption that approvals will be 120 days sooner. About $1 million of the $1.7 million in savings is a result of the shorter time for approval. These savings, however, may be offset by about $700,000 in costs each year for the preparation of full summaries. The summary, along with the separation of the NADA into technical sections, will lead to a faster and more efficient review by facilitating concurrent reviews of the NADA. If the agency's estimate of the value of earlier approvals turns out to be optimistic, the net impact of the changes in the regulations would move closer to zero.

Based on this analysis, the agency concludes that the proposed regulations do not constitute a major rule, as defined in Executive Order 12291. The agency also certifies, in accordance with section 605(b) of the Regulatory Flexibility Act, that there will not be a significant impact on a substantial number of small entities, and, therefore, that a Regulatory Flexibility Analysis is not required. An assessment of the economic impact of this proposed rule has been placed on file in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1980

The proposed rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. Existing information requirements in the following sections of this proposed rule have been approved by OMB under the control numbers indicated: 514.50 (d)(4) and (d)(5), OMB 0910–0032; 514.50(d)(8), OMB 0910–0190; 514.51, OMB 0910–0011; 514.200, OMB 0910–0191; 514.410, 0910–0117; 514.420, OMB 0910–0001. Information requirements in § 514.410 were approved under OMB 0910–0204 which has expired. The remaining information requirements, discussed below, have been submitted to OMB for review. The title and description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: New Animal Drug Regulations.

Description: The information requirements contained in the proposed rule would collect information from persons who must obtain FDA approval prior to marketing new animal drug products. These persons must submit information in the form of applications and related submissions. FDA will use the information submitted to determine whether the proposed new animal drug is eligible for approval and marketing.

Description of Respondents: Businesses.

Estimated Annual Reporting and Recordkeeping Burden:

Section	No. of respondents	Annual No. of responses	Average burden per response	Annual burden hours
514.50				
(d)(1)	214	1,050	160	168,000
(d)(2)	214	70	650	45,500
(d)(3)(ii)	214	65	270	17,550
(d)(6)	214	48	370	17,760
(d)(7)	214	54	125	6,750
(f)	214	65	325	21,125
514.58	214	20	45	900
514.70	214	1,424	99	140,976
514.421	214	4	42	168
514.430	214	36	30	1,080
Total		2,836	2,116	419,809

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these information collection requirements. Organizations and individuals desiring to submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should direct them to FDA's Dockets Management Branch (address above), and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

X. Text of the Proposed Rule

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 12

Administrative practice and procedure.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 511

Animal drugs, Medical research, Reporting and recordkeeping requirements.

21 CF Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR parts 10, 12, 16, 20. 500, 510, 511, and 514 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 is revised to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 530–542, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–706; 28 U.S.C. 2112.

§ 10.25 [Amended]

2. Section 10.25 *Initiation of administrative proceedings* is amended in paragraph (a)(1) by removing "§ 514.1" and replacing it with "§ 514.50".

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

3. The authority citation for 21 CFR part 12 is revised to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50. 141–149. 467f. 679, 821, 1034; secs. 2, 351, 361 of the Public Health

Service Act (42 U.S.C. 201, 262, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–706; 28 U.S.C. 2112.

§ 12.21 [Amended]

4. Section 12.21 *Initiation of a hearing involving the issuance, amendment, or revocation of an order* is amended in paragraph (a)(2) by removing "§ 514.1" and "§ 514.2" and replacing them with "§ 514.50" and "§ 514.51", respectively.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

5. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451 1461); 28 U.S.C. 2112.

§ 16.1 [Amended]

6. Section 16.1 *Scope* is amended in paragraph (b)(2) by removing the entry for "§ 514.210."

PART 20—PUBLIC INFORMATION

7. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

§ 20.100 [Amended]

8. Section 20.100 is amended by revising the section heading, in paragraph (c)(10) by removing "§ 514.12" and replacing it with "§ 514.430", in paragraph (c)(11) by removing "§ 514.11" and replacing it with "§ 514.430", and in paragraph (c)(12) by removing "§ 514.10" and replacing it with "§ 514.430" to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

PART 500—GENERAL

9.–11. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

§ 500.25 [Amended]

12. Section 500.25 *Anthelmintic drugs for use in animals* is amended in paragraph (c) by removing "§ 514.8(d) and (e)" and "§ 514.9" and replacing them with "§ 514.70" and "§ 514.75", respectively.

PART 510—NEW ANIMAL DRUGS

13. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 378).

§ 510.7 [Amended]

14. Section 510.7 *Consignees of new animal drugs for use in the manufacture of animal feed* is amended in paragraphs (a)(1) and (a)(2) by removing "§ 514.2" and replacing it with "§ 514.51".

Subpart C [Removed and Reserved]

15. Subpart C, consisting of § 510.200 is removed and reserved.

§ 510.305 [Removed]

16. Section 510.305 *Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs* is removed from Subpart D.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

17. The authority citation for 21 CFR part 511 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 360b, 371).

18. Section 511.2 is added to read as follows:

§ 511.2 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an investigational new animal drug (INAD) notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.430 of this chapter.

19. Part 514 is revised to read as follows:

PART 514—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW ANIMAL DRUG

Subpart A—General Provisions

Sec.
514.1 Scope of this part.
514.2 Purpose.
514.3 Definitions.

Subpart B—Applications

514.50 Content, format, and summary of a new animal drug application.
514.51 Application for an animal feed bearing or containing a new animal drug.
514.58 Minor use application.
514.60 Amendment of an unapproved application.
514.65 Withdrawal by the applicant of an unapproved application.
514.70 Supplements and other changes to an approved application.
514.71 Procedure for submission of a supplement to an approved application.
514.72 Change in ownership of an application.
514.75 Supplemental application for an animal feed bearing or containing a new animal drug.
514.83 Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs.
514.90 Waivers.

Subpart C—FDA Actions on Applications

514.100 Review of an application.
514.101 Filing an application.
514.102 Communications between FDA and an applicant.
514.103 Dispute resolution.
514.104 Drug with potential for abuse.
514.105 Approval of an application.
514.106 Categories of supplemental applications.
514.107 Foreign data.
514.110 Approvable letter to the applicant.
514.120 Not approvable letter to the applicant.
514.125 Refusal to approve an application.
514.126 Adequate and well-controlled studies.
514.129 Incomplete application for an animal feed bearing or containing a new animal drug.
514.150 Withdrawal of approval of an application.
514.152 Notice of withdrawal of approval of an application for a new animal drug.
514.160 Approval or reinstatement of an application for which approval was refused, suspended, or withdrawn.
514.170 Adulteration and misbranding of an approved animal drug.

Subpart D—Hearing Procedures for New Animal Drugs

514.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.
514.201 Procedure for hearings.
514.235 Judicial review.

Subpart E—[Reserved]

Subpart F—Miscellaneous Provisions

514.410 Imports and exports of a new animal drug.
514.420 Drug master file.
514.421 Public master file.
514.430 Availability for public disclosure of data and information in an application.
514.440 Addresses.
514.445 Guidelines.

Authority: Secs. 501, 502, 512, 701, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 376, 381).

Subpart A—General Provisions

§ 514.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and review by, the Food and Drug Administration (FDA) of applications, and amendments and supplements to them, by persons seeking or holding approval from FDA of the following:

(1) An application under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) to market a new animal drug.

(2) An application under section 512(m) of the act to manufacture an animal feed containing a new animal drug.

(b) This part does not apply to an animal drug produced and distributed in full conformance with the Animal Virus, Serum, and Toxin Law of March 4, 1913 (37 Stat. 832 as amended (21 U.S.C. 151 *et seq.*)).

(c) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 514.2 Purpose.

The purpose of this part is to establish an efficient and thorough new animal drug review process to facilitate the approval of any new animal drug that is shown to be safe and effective for its intended use, to ensure the disapproval of any new animal drug that is not shown to be safe and effective for its intended use, and to facilitate the withdrawal of approval of any new animal drug that is no longer shown to be safe and effective for its intended use. These regulations shall be construed in the context of these objectives.

§ 514.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in §§ 510.3 and 558.3 of this chapter apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–903 (21 U.S.C. 321–394)).

Animal drug product means a finished dosage form, for example, tablet, capsule, powder or solution, or a Type A medicated article that contains an animal drug substance, generally, but not necessarily, in association with one or more other ingredients.

Animal drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of an animal's body, but does not include intermediates used in the synthesis of such ingredient.

Animal feed means an animal feed bearing or containing a new animal drug as provided in part 558 of this chapter.

Applicant means any person who submits an application under this part to obtain FDA approval to market a new animal drug or an animal feed bearing or containing a new animal drug or any person who owns an approved application.

Application means the applications described under §§ 514.50 and 514.51; and the minor use application described under § 514.58; "application" includes all amendments and supplements. "Application" also includes applications approved under the DESI program.

Approvable letter means a written communication to an applicant from FDA stating that FDA will approve the application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of an application or any part of an application and does not permit marketing of the animal drug product that is the subject of the application.

Approval letter means a written communication to an applicant from FDA approving an application. An approval letter permits marketing of the animal drug product that is the subject of the application, except in the case of an application for approval of a Category II Type A medicated article.

Approval upon publication of a regulation applies to a Category II Type A medicated article. A regulation under section 512(i) of the act must be published before an application for a Type B or Type C medicated feed as described in § 514.51 may be submitted.

CVM means Center for Veterinary Medicine.

FDA means the Food and Drug Administration.

MFA means a medicated feed application as described in § 514.51 and includes all amendments and supplements.

Minor species means an animal other than cattle, horses, swine, chickens, turkeys, dogs, and cats. Sheep are a minor species with respect to effectiveness and animal safety data collection requirements; sheep are a major species with respect to human food safety data collection requirements arising from the possible presence of drug residues in food.

Minor use means the use of a new animal drug in a minor animal species or the use of a new animal drug in any animal species for the control of a disease that occurs infrequently or that occurs in limited geographic areas.

NADA means a new animal drug application as described in § 514.50 and includes all amendments and supplements.

New animal drug substance means any substance that, when used in the manufacture, processing, or packing of an animal drug, causes that animal drug to be a new animal drug, but does not include intermediates used in the synthesis of such substance.

Not approvable letter means a written communication to an applicant from FDA stating that FDA does not consider the application approvable because one or more deficiencies in the application preclude FDA from approving it.

Subpart B—Applications

§ 514.50 Content, format, and summary of a new animal drug application.

An application to be filed pursuant to section 512(b) of the act shall be submitted in the form and shall contain the information, as appropriate for the particular submission, required under this section. Two copies of the entire application are required, an archival copy and a review copy. An additional copy of the chemistry, manufacturing, and controls section is required to facilitate preapproval inspection of the manufacturing facility. An application for a new animal drug will generally contain an application form, an index, a summary, six to eight technical sections, case report tabulations of animal data, case report forms, and labeling. Certain applications may contain only some of those items, and information will be limited to that needed to support the particular submission. The application is required to contain reports of all investigations of the animal drug product sponsored by the applicant, and all other information about the animal drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any

source. FDA will maintain guidelines on the format and content of applications to assist applicants in preparing them.

(a) *Application form.* The applicant shall submit a completed and signed application form (Form FDA 356V) that contains the following:

(1) The name and address of the applicant; the date of the application; the application number if previously issued (for example, if the application is a resubmission, an amendment, or a supplement); the name of the new animal drug product, including its established, proprietary, code, and chemical names; the dosage form and strength; the route of administration; the identification numbers of all investigational new animal drug applications that are referred to in the application; the identification number of all drug master files and other applications under this part that are referred to in the application; and the new animal drug product's proposed indications for use.

(2) A statement whether the submission is an original submission under § 514.50, a resubmission under § 514.50, a minor use application under § 514.58, an amendment under § 514.60, or a supplement under § 514.70.

(3) A statement whether the applicant proposes to market the new animal drug product as a prescription or an over-the-counter product, and a justification for marketing the new animal drug product as a prescription or an over-the-counter product, as appropriate.

(4) A checklist identifying what enclosures required under this section are being submitted.

(5) The applicant, or the applicant's attorney, agent, or other authorized official, shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application shall contain the name and address of, and to be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States. WARNING: A willfully false statement is a criminal offense (18 U.S.C. 1001).

(b) *Index.* The archival copy of the application shall contain an index by volume number and page number to the summary under paragraph (c) of this section, the technical sections under paragraph (d) of this section, and the supporting information under paragraph (f) of this section.

(c) *Summary.* (1) An application shall contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and information in the application, including an understanding of the quantitative aspects of the data. A summary is required for an application under § 514.50, a minor use application under § 514.58, and a supplement under § 514.70(b) or (c). A summary is not required for a supplement under § 514.70(d) or (e). If an application is resubmitted, the application shall contain an updated summary, as appropriate. The summary shall contain a discussion of all aspects of the application and shall abstract the information into a well-structured and unified document. FDA may furnish the summary to FDA advisory committee members and other FDA officials whose duties require an understanding of the application. To the extent possible, data in the summary are required to be presented in tabular or graphic form. The summary required under this paragraph may be used by FDA or the applicant to prepare the freedom of information summary for public disclosure (under § 514.430(e)(2)(ii)) when the application is approved.

(2) The summary shall contain the following information:

(i) The proposed text of the labeling for the new animal drug product, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, including the statement that the product is a prescription or an over-the-counter product.

(ii) A statement identifying the pharmacologic class of the new animal drug product and a discussion of the scientific rationale for the new animal drug, its intended use, and the potential benefits and risks of the new animal drug product.

(iii) A brief description of the marketing history, if any, of the new anima1 drug product outside the United States, including a list of the countries in which the product has been marketed, a list of any countries in which the product has been withdrawn from marketing including an explanation of the reason for such withdrawal, and a list of countries in which applications for marketing are pending. The description is required to include both marketing by the applicant and, if known, the history of marketing by other persons.

(iv) A summary of the chemistry, manufacturing, and controls section of the application.

(v) A summary of the effectiveness section of the application, including the results of all statistical analyses of the clinical trials.

(vi) A summary of the target animal safety section of the application.

(vii) A summary of the residue toxicology section of the application.

(viii) A summary of the residue chemistry section of the application.

(ix) A summary of the target animal pharmacokinetics and bioavailability section of the application.

(x) A summary of the microbiology section of the application (for anti-infective new animal drugs only).

(xi) A summary of the environmental impact section of the application.

(xii) A concluding discussion that presents the benefit and risk considerations related to the new animal drug, including a discussion of any proposed additional studies or surveillance the applicant intends to conduct following approval of the application.

(d) *Technical sections.* The application shall contain the technical sections described below. Each technical section shall contain data and information in sufficient detail to permit FDA to make a knowledgeable judgment about whether to approve the application or whether grounds exist under section 512(d) of the act to refuse to approve the application. The required technical sections are as follows:

(1) *Chemistry, manufacturing, and controls section.* A section describing the composition, manufacture, and specifications of the animal drug substance and the animal drug product, including the following:

(i) *Animal drug substance.* A full description of the animal drug substance including its physical and chemical characteristics and stability; the name and address of the manufacturer; the method of synthesis or fermentation, isolation, and purification of the animal drug substance; the process controls used during manufacture and packaging; such specifications and analytical methods as are necessary to ensure the identity, strength, quality, and purity of the animal drug substance; the sterility, particle size, crystalline form, and stability of the new animal drug substance; and the bioavailability of the new animal drug products made from the animal drug substance. In addition, the application may provide for the use of alternatives to meet any of these requirements, including alternative sources, process controls, methods, and specifications. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary or a master file may satisfy relevant requirements in this paragraph.

(ii) *New animal drug product.* A list of all components used in the manufacture of the new animal drug product (regardless of whether they appear in

the product) and a statement of the composition of the product; a statement of the specifications and analytical methods for each component; the name and address of each manufacturer of the new animal drug product; a description of the manufacturing and packaging procedures and in-process controls for the product including a list of relevant manufacturing and laboratory equipment and an explanation of the raw material and batch control number system; such specifications and analytical methods as are necessary to ensure the identity, strength, quality, purity including specifications relating to sterility, bioavailability, and dissolution rate of the animal drug product; specifications relating to containers and closure systems; and stability data with proposed expiration dating. In addition, the application may provide for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, in-process controls, methods, and specifications. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary or a master file may satisfy relevant requirements in this paragraph.

(iii) *Early submission.* The applicant may submit a complete chemistry, manufacturing, and controls section 90 to 120 days before the anticipated submission of the remainder of the application. FDA will review such early submissions as resources permit.

(2) *Effectiveness section.* A section describing the studies conducted to demonstrate the effectiveness of the animal drug for its intended use, including the following:

(i) A description and analysis of each controlled clinical study pertinent to a proposed use of the new animal drug product, including the protocol for the study and when necessary a description of the statistical analyses used to evaluate the study. If the study report is an interim analysis, that fact is to be noted and a projected completion date provided. A description of each controlled clinical study that has not been analyzed in detail for any reason (e.g., because it has been discontinued or is incomplete) is to be included in this section, together with a copy of the protocol for the study, a brief description of the results and status of the study, and an explanation of why the study has not been analyzed in detail.

(ii) A description of each uncontrolled clinical study, a summary of the results, and a brief statement explaining why the study is classified as uncontrolled.

(iii) A description and analysis of any other data or information relevant to an evaluation of the effectiveness of the new animal drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations (including controlled and uncontrolled studies of uses of the new animal drug other than those proposed in the application), commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(iv) An integrated analysis of the data demonstrating substantial evidence of effectiveness for the claimed indications. Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended, and modifications for specific subgroups (for example, young animals, older animals, debilitated, or diseased animals). The analysis shall include a discussion of the benefits and risks of the animal drug, and an explanation of why the benefits exceed the risks under the conditions stated in the labeling.

(v) If the new animal drug product is a combination of previously investigated or approved new animal drugs, an integrated summary of preexisting information obtained from nonclinical and clinical investigations and from experience with its components. Such summary is required to include an adequate bibliography of publications about the components and may incorporate information concerning such components previously submitted to FDA by the applicant. With written authorization, the applicant may also incorporate information which another applicant has on file with FDA. Substantial evidence is required to show that each ingredient designated as active in any new animal drug combination makes a contribution to the effect in the manner claimed or suggested in the labeling. Further, if in the absence of express labeling claims of advantages for the combination, such a product purports to be better than either component alone, substantial evidence is required to show that the new animal drug has that purported effectiveness.

(vi) If the applicant has transferred any obligations for the conduct of any clinical study to a contract research organization, the application is required to include a statement containing the name and address of the contract research organization, identifying the clinical study, and listing the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(vii) If original subject records were audited or reviewed by the applicant in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the applicant, the applicant shall submit a list identifying each clinical study so audited or reviewed.

(3) *Target animal safety section.* (i) A section describing the investigations of the new animal drug to determine its safety to the target species, including the following:

(A) A description and analysis of each nonclinical and clinical pharmacology study of the new animal drug, including a brief comparison of the results of the target animal studies with the laboratory animal pharmacology and toxicology data.

(B) A description and analysis of any other data or information relevant to an evaluation of the safety of the new animal drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations (including controlled or uncontrolled studies of uses of the new animal drug other than those proposed in the application), commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(C) An integrated analysis of all available information about the safety of the new animal drug product including pertinent data from studies in laboratory animals, demonstrated or potential adverse effects of the new animal drug, clinically significant interactions with other animal drugs, and other safety considerations, such as data from epidemiological studies of related animal drugs. A description of any statistical analyses performed in analyzing safety data is also required, unless such description is already included under paragraph (d)(2)(i) of this section.

(D) For each nonclinical laboratory study a statement that it was conducted in compliance with the good laboratory practice regulations in part 58 of this chapter, or, if the study were not conducted in compliance with those regulations, a statement explaining the noncompliance.

(E) If the new animal drug has a potential for abuse, a description and analysis of studies or information related to abuse of the new animal drug, including a proposal for its scheduling

under the Controlled Substances Act. A description of any studies relating to overdosage, including information on antidotes or other treatments, if known, is also required.

(ii) The applicant shall periodically update its pending application with new safety information concerning the new animal drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. These "safety update reports" are required to include the same kinds of information (from clinical studies, laboratory animal studies, and other sources) and are required to be submitted in the same format as the integrated analysis in paragraph (d)(3)(i)(C) of this section. In addition, the safety update reports are required to include the case report forms for each animal or group of animals, including those which did not complete the study. The applicant shall submit these reports 4 months after the initial submission; following receipt of an approvable letter; and at other times as requested by FDA. Prior to the submission of the first such report, applicants are encouraged to consult with FDA regarding further details on its form and content.

(4) *Residue toxicology section.* A section containing the data necessary to assess the safety of food derived from animals treated with the new animal drug product. To permit such assessment, the applicant shall submit the following kinds of studies:

(i) Studies of the toxicological effects of the new animal drug as they relate to the new animal drug's intended uses, including, as appropriate, studies assessing the following: acute, subacute, and chronic toxicity; carcinogenicity; genetic toxicity; and any toxicity related to the new animal drug's particular mode of administration or conditions of use.

(ii) Studies, as appropriate, of the effects of the new animal drug on reproduction and on the developing fetus.

(iii) For each nonclinical laboratory study, a statement that it was conducted in compliance with the GLP regulations in part 58 of this chapter, or, if the study were not conducted in compliance with those regulations, a statement explaining the noncompliance.

(5) *Residue chemistry section.* A section describing the new animal drug residue methods and studies, including the following:

(i) A description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of the drug's use. When data or other adequate information establish that it is not reasonable to expect the new animal drug (other than a carcinogen or a possible carcinogen) to become a component of food at concentrations FDA considers unsafe, a regulatory method is not required.

(ii) Studies on the absorption, distribution, metabolism, and excretion of the new animal drug in laboratory animals as well as in the target species.

(iii) The proposed tolerance or withdrawal period or other use restrictions to ensure that the proposed use of the new animal drug product will be safe.

(iv) A new animal drug that is for use in food-producing animals and that is a carcinogen or a possible carcinogen is required to satisfy the applicable requirements of subpart E of part 500 of this chapter.

(6) *Pharmacokinetics and bioavailability section.* A section describing the animal pharmacokinetic data and animal bioavailability data, including the following:

(i) A description of each of the bioavailability and pharmacokinetic studies of the new animal drug in the target species performed by or on behalf of the applicant, including a description of the analytical and statistical methods used in each study.

(ii) If the application describes in the chemistry, manufacturing, and controls section specifications or analytical methods needed to ensure the bioavailability of the new animal drug product or animal drug substance, or both, a statement in this section of the rationale for establishing the specifications or analytical methods, including data and information supporting the rationale.

(iii) A summarizing discussion and analysis of the pharmacokinetics of the active ingredients and the bioavailability of the new animal drug product.

(7) *Microbiology section.* If the new animal drug is an anti-infective, a section describing the microbiology data, including the following:

(i) A description of the biochemical basis of the new animal drug's action on microbial physiology.

(ii) A description of the antimicrobial spectrum of the new animal drug, including results of in vitro preclinical studies to demonstrate concentrations of the drug required for effective use.

(iii) A description of any known mechanisms of resistance to the new animal drug, including results of any known epidemiologic studies to demonstrate prevalence of resistance factors.

(iv) A description of clinical microbiology laboratory methods (for example, in vitro susceptibility discs) needed for effective use of the new animal drug.

(v) A description of the data that satisfy the criteria in § 558.15 of this chapter concerning the safety of subtherapeutic uses of antibacterial drugs in animal feeds.

(8) *Environmental impact section.* The application shall contain either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(e) *Samples and labeling*—(1) *Samples.* Upon request from FDA, the applicant shall submit samples of the new animal drug substance, the new animal drug product, and any required ingredient used as a component and any pertinent information concerning them for physical review and/or testing. Whenever FDA decides to conduct a validation trial of the applicant's methods and specifications, FDA will advise the applicant of the necessary requirements.

(2) *Labeling.* The applicant shall submit the following in the archival copy of the application:

(i) Copies of the label and all other labeling for the new animal drug product (2 copies of draft labeling and 6 copies of final printed labeling).

(ii) Labeling for new animal drugs intended for use in the manufacture of medicated feeds shall include:

(A) Specimens of labeling to be used for the new animal drug (i.e., Type A medicated article) with adequate directions for the mixing and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, or in any of the advertising, sponsored by the applicant. Ingredient labeling may utilize collective names as provided in § 501.110 of this chapter.

(B) Representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.

(f) *Case report forms and tabulations.* The archival copy of the application shall contain the following case report tabulations and case report forms:

(1) *Case report tabulations.* The application shall contain tabulations of the data from each adequate and well-controlled study under § 514.126 and from other studies which are intended to provide corroborative information. The tabulations shall include the data on each animal or group of animals in each study.

(2) *Case report forms.* The application shall contain a copy of the case report

form for each animal or group of animals, including an animal or a group of animals receiving a reference drug (i.e., Type A medicated article) or a placebo. A case report form for any animal or group of animals which did not complete the study is also required.

(g) *Other.* The following apply to the submission of information.

(1) An applicant is invited to meet with FDA before submitting an application to discuss the presentation and format of supporting information. FDA requests that all conferences and meetings be scheduled in advance.

(2) The applicant ordinarily is not required to resubmit information previously submitted, but may incorporate the information. A reference to information submitted previously shall identify FDA's file by name, reference number, volume, and page number where the information can be found. A reference to information submitted to FDA by a person other than the applicant shall be accompanied by a written statement that authorizes the reference and that is signed by the person who submitted the information.

(3) For each part of the application that is not in English, the applicant shall submit both an accurate and complete English translation and the original foreign language publication.

(4) With prior FDA concurrence, an applicant may submit, on microfiche or electronic media, the portions of the archival copy of the application described in paragraphs (b) through (d) of this section and tabulations of data and case report forms, described in paragraph (f) of this section. Information relating to samples and labeling, described in paragraph (e) of this section, is required to be submitted in hard copy.

(h) *Format of an original application.* (1) An applicant shall submit a complete archival copy of the application that contains the information required under paragraphs (a) through (f) of this section. FDA will maintain intact the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other FDA personnel access to the application for official business, and to maintain in one place a complete copy of the application.

(2) The applicant shall submit a review copy of the application. Each of the technical sections described in paragraphs (d)(1) through (d)(8) of this section is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section. The applicant may obtain from FDA sufficient colored binders to contain the archival and review copies of the application.

§ 514.51 Application for an animal feed bearing or containing a new animal drug.

(a) An application submitted under section 512(m) of the act shall be completed, signed, and submitted in triplicate in a Form FDA 1900 as described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B or Type C medicated feed, as defined in § 558.3 of this chapter, shall include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill. If an approved List Master File (LMF) as defined in § 514.75(d) is in effect, the applicant shall reference the LMF by stating "See LMF (LMF number) submission of (date)." Simultaneously, the applicant shall make a supplemental submission to the LMF as provided in § 514.75(d).

(3) Whether the submission is an original or supplemental application.

(4) Identification of the Type A medicated article, as defined in § 558.3 of this chapter, used by generic name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal crumbles, pellets, liquid, or other specified form.

(7) Whether the feed is a Type B or Type C medicated feed.

(8) Whether the feed is for sale or for own use (not for sale).

(9) Level of the drug(s) in the finished feed, and the amount of Type A medicated article per ton contained therein.

(10) Identification of the regulation(s) in part 558 of this chapter on which approval relies. In addition, § 510.515 of this chapter may provide a basis on which approval of the application relies.

(11) Labeling representative of each intended use as stated in the claim. Each generic label shall include, in addition to other required information, the claim, drug level, mixing directions, feeding directions, caution and/or warning statements, and any other special directions required by the published regulation. The labeling shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(12) A commitment to establish and maintain a program of sampling and analysis consisting of an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the date of manufacture of the medicated feed.

(13) A statement of the minimum and maximum assay value permitted from the labeled amount of the drug.

(14) Identification of the agent authorized to act on behalf of the applicant.

(15) The applicant's name, responsible individual's title and original signature, and date.

(c) Upon approval, one copy of the application will be signed by an authorized employee of FDA and returned to the applicant.

§ 514.58 Minor use application.

(a) An application submitted under this section is intended for approval of a "minor use" as defined in § 514.3.

(b) A minor use application shall include the same information as an application filed under § 514.50, except that, where FDA determines that it is scientifically appropriate, the data required to establish target animal safety, target animal effectiveness, or human food safety may be obtained through the use of animal models and the extrapolation of data from a major species. Information gathered with public funds may be made available for incorporation from a "Public Master File."

(c) Guidelines for the preparation and submission of data to satisfy the requirements of section 512 of the act regarding target animal safety and effectiveness, human food safety, and environmental considerations for new animal drugs intended for a "minor use" are available from the Industry Information Branch (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(d) Where the guidelines do not specifically provide for a particular "minor use," CVM will, upon request, attempt to advise interested persons of the data that are required for the minor use and that will satisfy the requirements of section 512 of the act.

§ 514.60 Amendment of an unapproved application.

An applicant may submit an amendment to an unapproved application that has been accepted for

filing under §514.101. The submission of a major amendment (for example, an amendment that contains significant new data from a previously unreported study or detailed new analyses of previously submitted data), whether on the applicant's own initiative or at FDA's invitation, constitutes an agreement by the applicant under section 512(c) of the act to extend the review period for the application. Ordinarily, FDA will extend the review period for a major amendment, but only for the time necessary to review the new information. However, FDA may not extend the review period for more than 180 days. If FDA extends the review period, the director of the primary review division will notify the applicant of the length of the extension. The submission of an amendment that is not a major amendment will not cause the review period to be extended. Normally, submission of updated safety data under § 514.50(d)(3)(ii) will not cause any extension of the review period.

§ 514.65 Withdrawal by the applicant of an unapproved application.

By notifying FDA in writing, an applicant may at any time withdraw an application that is not approved. FDA will deem an applicant's failure to respond within 60 days to an approvable letter under § 514.110 or a not approvable letter under § 514.120 to be a withdrawal of the application by the applicant. Such a withdrawal is without prejudice to refiling. FDA will retain the application and will provide a copy to the applicant on request under the fee schedule of FDA's public information regulations in § 20.42 of this chapter.

§ 514.70 Supplements and other changes to an approved application.

(a) *Changes in an approved application.* An applicant shall notify FDA about each change in the conditions established in an approved application that differs from any variation already provided for in the application. The notification to FDA shall fully describe the change. Depending on the type of change, the applicant shall notify FDA by submission of a supplemental application under paragraph (b) or (c) of this section or by inclusion of the information in a periodic drug experience report (DER) to the application submitted under paragraph (d) of this section. Notwithstanding the requirements of paragraphs (b) and (c) of this section, an applicant shall make a change described in one of those paragraphs (for example, the deletion of an ingredient common to many animal drug products) if the change is required by regulation, and may make a change described in one of those paragraphs if the change is provided for by a guideline or notice that is published or announced in the **Federal Register**, where the regulation, guideline, or notice provides for a less burdensome notification of the change (for example, by notification at the time a supplement is submitted or in the next annual report).

(b) *Supplements requiring FDA approval before the change is made.* An applicant shall submit a supplement and obtain FDA approval of the supplement before making any of the changes listed below:

(1) *Animal drug substance.* A change affecting the animal drug substance to accomplish any of the following:

(i) To relax the limits for a specification;

(ii) To establish a new analytical method;

(iii) To delete a specification or analytical method;

(iv) To change the synthesis, fermentation, or isolation of the animal drug substance;

(v) To use a different facility or establishment to manufacture, process, or package the animal drug substance, where:

(A) The manufacturing process in the new facility or establishment differs from that approved in the application;

(B) The animal drug substance is intended to be administered to animals as a biomass product; or

(C) The new facility or establishment has not received a satisfactory current good manufacturing practice (CGMP) inspection within the previous 2 years covering that manufacturing process.

(2) *New animal drug product.* A change affecting the new animal drug product to accomplish any of the following:

(i) To add or delete an ingredient, or otherwise to change the composition of the product, other than deletion of an ingredient intended to affect only the color of the product;

(ii) To relax the limits for a specification;

(iii) To establish a new analytical method;

(iv) To delete a specification or analytical method;

(v) To change the method of manufacture of the new animal drug product, including changing or relaxing an in-process control;

(vi) To use a different facility or establishment, including a different contract laboratory or labeler, to manufacture, process, or package and label the product;

(vii) To change the container and closure system for the product (for example, glass to high density polyethylene or high density polyethylene to polyvinyl chloride) or change a specification or analytical method for the container and closure system;

(viii) To change the size of the container, except for solid oral dosage forms, without a change in the approved container and closure system;

(ix) To extend the expiration date of the product based on data obtained under a new or revised stability testing protocol that has not been approved in the application;

(x) To establish a procedure for reprocessing a batch of the product that fails to meet specifications.

(3) *Labeling.* Any change in labeling, except one described in paragraph (c)(2) or (d) of this section. Examples of labeling changes not described in paragraph (c)(2) or (d) of this section and that therefore require FDA approval prior to implementation include a revision in labeling such as updating information pertaining to effects, dosages, side effects and contraindications, which includes information headed "side effects," "warnings," "precautions," and "contraindications."

(4) *Multiple changes.* Any number of changes may be submitted at any one time, but if they fall into different categories as listed in paragraphs (b)(1)(i) through (b)(1)(v) of this section, the proposed changes are to be covered by separate supplements. Where, however, a change necessitates an overlap in categories, it should be submitted in a single supplement. For example, a change in tablet potency would require other changes such as in components, composition, and labeling, and should be submitted in a single supplement.

(c) *Supplements for changes that may be made before FDA approval.* Changes made under this section are applicable to new animal drug substances and finished dosage form new animal drug products. A supplement for a change made before FDA approval requires a full explanation of the basis for the change and a statement of the date on which the change was made. If the change concerns labeling, the applicant shall submit final printed labeling. The applicant shall promptly revise all promotional labeling and drug advertising to make it consistent with any change in the labeling. The supplement and its mailing cover are to be plainly marked: "Special Supplement—Changes Being Effected."

An applicant shall submit a supplement at the time the applicant makes any of the kinds of changes listed below in the conditions in an approved application.

(1) Add a new specification or test method or make a change in the manufacturing procedures or controls to provide increased assurance that the new animal drug substance or product will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess;

(2) Change in labeling to accomplish any of the following:

(i) To add or strengthen a contraindication, warning, precaution, or adverse reaction statement;

(ii) To add or strengthen a statement about drug abuse or overdosage;

(iii) To add or strengthen an instruction about dosage or administration that is intended to increase the safe use of the product;

(iv) To delete false, misleading, or unsupported indications for use or claims for effectiveness.

(3) To use a different facility or establishment to manufacture the animal drug substance, where:

(i) The manufacturing process in the new facility or establishment does not differ from that approved in the application;

(ii) The animal drug substance is not a biomass product; and

(iii) The new facility or establishment has received a satisfactory current good manufacturing practice inspection within the previous 2 years covering that manufacturing process.

(d) *Changes that may be described in a drug experience report.* Other than a change described in paragraphs (b) and (c) of this section, an applicant may describe the following kinds of changes in the next periodic drug experience report required under §§ 514.80, 514.81, and 514.82:

(1) Changes in the specifications or methods for active and inactive ingredients to bring them into compliance with current specifications or methods in the current official compendium.

(2) A different container size for solid oral dosage forms (e.g., tablets and capsules) where the container and closure are of the same materials as those provided for in the approved application.

(3) Change in equipment that does not alter the approved method of manufacture of a new animal drug.

(4) Change from one batch size to another without any change in manufacturing procedure unless the change involves greater than a tenfold increase in batch size.

(5) Change to more stringent specifications without altering the method described in the approved application.

(6) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(7) Initiation of a product identification coding system.

(8) Change from paper labels to direct printing on glass or other kinds of immediate containers without a change in text.

(9) Extension of the current expiration date based on full shelf-life data obtained using a stability protocol approved in the application.

(10) Addition of precautionary statements, explanations, and clarifications to manufacturing and control procedures.

(11) Minor editorial or similar minor label changes, such as changes in the ink colors of labeling, the addition of the FDA approval statement (including the NADA number), changes in the placement of the text on the label as long as FDA label guidelines are followed, the revision or updating of a company logo or label design, and the correction of typographical errors.

(12) Changes in the marking of solid oral dosage forms which do not result in any changes in the labeling or approved specifications for the product.

(13) Reduction or elimination of manufacturing overages for drug and nondrug ingredients.

(14) Changes in suppliers of inactive ingredients, containers, or closures provided the products of the new suppliers meet criteria approved in the application.

(15) Changes in the in-plant coding and control number systems; e.g., material and product identification codes, lot numbering systems of raw materials, product specifications, or method codes.

(16) Changes in outer packaging material, such as carton shape, color, or style of printing which do not decrease the degree of protection of the drug, modify the text of approved labeling, or decrease the legibility of print.

(17) Changes in or replacement of noncompendial specifications and methods for ingredients, except those used for the determination of identity, potency, purity, sterility, or safety of the ingredients.

(e) *Changes permitted pending finalization of the National Academy of Sciences/National Research Council (NAS/NRC) review.* In addition to a change described in paragraph (c) of this section, a change proposed in a supplement to an NADA approved before October 10, 1962 may, upon written authorization from FDA, be implemented prior to approval of the supplement. The type of changes authorized by FDA in advance of approval are those that do not adversely affect, but may enhance the safety, effectiveness, quality, or stability of the product. A change may be permitted in advance of approval pending completion of the NAS/NRC review of the effectiveness of such drug and a determination as to whether there are grounds for refusing approval under section 512(d) of the act or for suspending or withdrawing approval under section 512(e) of the act. FDA will not take any action against a new animal drug or an applicant solely because changes that have been permitted in a written communication are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental application.

§ 514.71 Procedure for submission of a supplement to an approved application.

(a) Only the applicant may submit a supplement to an application.

(b) All procedures and actions that apply to an application under § 514.50 and a minor use application under § 514.58 also apply to a supplement, except that the information required in a supplement is limited to that needed to support a change. A supplement is required to include an application form and to contain an archival copy and a review copy, each with a summary when required and each with appropriate technical sections and labeling.

§ 514.72 Change in ownership of an application.

(a) An applicant may transfer ownership of its application. At the time of transfer, the new and former owners are required to submit the following information to FDA:

(1) The former owner shall submit a letter or other document stating that all rights to the application have been transferred to the new owner and the date on which the transfer is effective.

(2) The new owner shall submit a signed application and a letter or other document containing the following:

(i) The new owner's commitment to comply with all agreements, promises, and conditions made by the former owner and contained in the application;

(ii) The date that the change of ownership is effective; and

(iii) Either a statement that the new owner has a complete copy of the application, including supplements and

records that are required to be kept under § 514.80, or a request for a copy of the application from FDA's files. FDA will provide a copy of the application to the new owner under the fee schedule in § 20.42 of FDA's public information regulations.

(b) Once FDA has received the information specified in paragraph (a) of this section, FDA will not honor a request that ownership not be transferred, or, after the effective date of the change in ownership, that the transfer be withdrawn, unless both the former owner and the new owner request in writing that ownership not be transferred or that the transfer be withdrawn.

(c) The new owner shall submit a supplemental application under § 514.70 for any change in the conditions in the approved application, except the new owner may advise FDA in a specia1 drug experience report about a change in the animal drug product's label or labeling to change the product's brand or the name of its manufacturer, packer, or distributor as provided in §§ 514.70 and 514.80.

(d) FDA will publish in the **Federal Register** a notice of the change of ownership pursuant to section 512(i) of the act. Any revision of § 510.600(c) of this chapter or a specific approval regulation will be published at this time.

§ 514.75 Supplemental application for an animal feed bearing or containing a new animal drug.

(a) The applicant shall submit a supplemental application for any change which deviates from the conditions under which the application was approved. Animal feed label changes based on § 514.70(c) may be put into effect prior to approval provided a supplemental application is submitted at the time the applicant makes the changes and the supplemental application and its mailing cover are plainly marked: "Special Supplement—Changes Being Effected."

(b) The applicant shall submit an MFA (Form FDA 1900) in triplicate, completing items 1—name of applicant, 2—address including zip code, 3—establishment registration number, 4—date last registered, 6—type of application, 20—certification, signed by responsible individual, and date, and each item for which a change is being proposed. For all other items, the applicant may insert "See previous MFA approval." If changes are proposed for item 5—additional mills (mill list), the applicant shall attach a revised mill list (stating the establishment registration number, establishment name and address including zip code, and date last registered for each mill).

(c)(1) Firms with multiple feed manufacturing facilities that have more than one approved application may establish a list (facilities) master file (LMF) to consolidate their mill list (item 5 of the MFA). The request, by letter, is required to be accompanied by a signed MFA in triplicate. The applicant shall complete items 1 through 5, and item 20. For item 5, the applicant shall provide an up-to-date mill list (stating the establishment registration number, establishment name and address including zip code, and date last registered for each mill) for each approved MFA. For item 6, the applicant should check the "original" box. For all other items, the applicant may insert "See previous MFA approvals."

(2) Future changes in the mill list for any of the referenced MFA's may be obtained by submitting to the LMF an MFA, in triplicate, completed as described in paragraph (c)(1) of this section except that the applicant shall complete item 6 with the previously established LMF number and a check in the "supplemental" box.

(d) If the only change proposed is the deletion of a mill from the mill list, the applicant shall submit a certification in triplicate to the appropriate MFA or LMF stating the establishment registration number, establishment name and address including zip code, date last registered, and a list of the affected MFA's. A mill that is deleted from the mill list may no longer manufacture any medicated feed that requires an approved MFA.

(e) Upon approval of an MFA, one copy will be signed by an authorized FDA employee and returned to the applicant.

§ 514.83 Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location on the premises of each establishment to which an approved MFA or supplemental MFA applies either:

(a) A copy of the approved MFA and a sample of the approved labeling; or

(b) Identification of the approved MFA in a single file or in a single readable document that includes:

(1) The MFA number and the date of approval;

(2) The name(s) of the Type A medicated article(s) and the concentration of the drug(s);

(3) The name(s) of the approved manufacturer(s) of the article(s);

(4) The concentration of the drug(s) in the Type B or C medicated feed; and

(5) A sample of the approved labeling.

§ 514.90 Waivers.

(a) An applicant may request FDA to waive any requirement in part 514. Under § 514.126(c), an applicant may request FDA to waive any criteria of an adequate and well-controlled study described in § 514.126(b).

(b) A request for waiver is required to be submitted with supporting documentation in an application, an amendment, or a supplement. The request for waiver shall show that the waiver is legally permissible and shall contain one of the following:

(1) A justification showing that the applicant's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(c) FDA may grant a waiver if it finds that the waiver is legally permissible and if it finds one of the following:

(1) The applicant's compliance with the requirement is unnecessary for FDA to evaluate the application or compliance cannot be achieved;

(2) The applicant's alternative submission satisfies the requirement; or

(3) The applicant's submission otherwise justifies a waiver.

Subpart C—FDA Actions on Applications

§ 514.100 Review of an application.

(a)(1) Upon receipt of an application submitted pursuant to section 512(b) of the act, FDA will assign a primary review division for the application. That division will be the applicant's agency contact during the review process.

(2) Within 180 days of receipt of the application, plus any extension of the review period, FDA will review it and send the applicant an approval letter under § 514.105, an approvable letter under § 514.110, or a not approvable letter under § 514.120. This 180-day review period is called the "review clock."

(3) During the 180-day review period, an applicant may withdraw an application under § 514.65. If an applicant withdraws an application and later resubmits it, FDA will handle it as a new application.

(4) The 180-day review period may be extended by mutual agreement between FDA and an applicant or, as provided in § 514.60, as the result of submission of a major amendment.

(5) The 180-day review period applies to the application described under § 514.50, the minor use application described under § 514.58, and the supplemental application described under § 514.70(b).

(b) Within 90 days of receipt of an application submitted pursuant to section 512(m) of the act, or an additional time period as mutually agreed, FDA will:

(1) Notify the applicant that the application is approved, or

(2) Give the applicant written notice of an opportunity for a hearing on a proposal to refuse approval of the application on one or more of the grounds specified in section 512(m)(3) of the act.

§ 514.101 Filing an application.

(a) Within 60 days after FDA receives an application submitted under section 512(b) of the act, FDA will determine whether the application may be filed. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review.

(b) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application applies, FDA will file the application. The date of filing will be the date 60 days after the date FDA received the application. The date of filing begins the 180-day period described in section 512(c) of the act. This 180-day period is called the "filing clock."

(c) If FDA refuses to file an application, FDA will notify the applicant in writing and state the reason for the refusal under paragraph (d) or (e) of this section. If FDA refuses to file the application under paragraph (d) of this section, the applicant may, within 30 days of the date of FDA's notification, request in writing an informal conference with FDA to discuss filing the application. If following an informal conference an applicant requests that FDA file the application, FDA will file the application over protest in accordance with paragraph (b) of this section, notify the applicant in writing, and review it as filed. If the application is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. An applicant need not resubmit an application that is to be filed over protest. If FDA refuses to file an application under paragraph (e) of this section, an applicant may amend the application and resubmit it, and FDA will make a determination under this section whether it may be filed.

(d) FDA may refuse to file an application if any of the following apply:

(1) The application does not contain a completed application form.

(2) The application is not submitted in the form required under §§ 514.50, 514.58, or § 514.70(b).

(3) The application is incomplete because it does not contain information required under section 512(b) of the act, or §§ 514.50, 514.58, or § 514.70(b).

(4) The application does not contain a complete environmental assessment that addresses each of the items specified in the applicable format under § 25.31 of this chapter, or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

(5) The application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement that each nonclinical laboratory study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, for each such study not conducted in compliance with part 58, a brief statement justifying the noncompliance.

(e) FDA will refuse to file an application if any of the following apply:

(1) The new animal drug product that is the subject of the submission is already covered by an approved application.

(2) The submission purports to be a minor use application under § 514.58, but the new animal drug product is not one for which FDA has determined under § 514.58(b) that the data required to establish target animal safety and effectiveness and human food safety may be obtained through the use of animal models and the extrapolation of data from a major species.

(3) The animal drug product is produced and distributed as a biologic in full conformance with the Animal Virus, Serum, and Toxin Law of March 4, 1913 (37 Stat. 832 as amended; 21 U.S.C. 151 *et seq.*).

(f) Within 180 days after the date of filing, plus the time the review period was extended (if any), FDA will either approve the application or issue a notice of opportunity for a hearing, if in response to an approvable letter or a not approvable letter, the applicant has asked FDA to provide an opportunity for a hearing on the application. This paragraph does not apply to an application that has been withdrawn by the applicant from FDA review.

§ 514.102 Communications between FDA and an applicant.

(a) *General principles.* During the course of reviewing an application, FDA may communicate with an applicant about scientific, policy, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate. Such communication will be appropriately documented in the application in accordance with § 10.65 of this chapter. Further details on the procedures for communications between FDA and an applicant are contained in the CVM Policy and Procedures Manual, which is publicly available.

(b) *Notification of easily correctable deficiencies.* FDA reviewers will make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, e.g., deficiencies concerning chemistry, manufacturing, and control issues. FDA will also inform applicants promptly of the need for more data or information or for technical changes in the application to facilitate FDA's review. FDA's communication of easily correctable deficiencies is intended to permit an applicant to correct such deficiencies relatively early in the review process and to allow the applicant to submit an amendment before the review period has elapsed. Such early communication will not normally apply to major scientific issues, which require consideration of the entire pending application by FDA officials as well as reviewing staff. FDA's communication of major scientific issues will normally be addressed in an action letter to the applicant.

(c) *Conferences.* With advance notice, meetings between FDA and an applicant may be held to inform an applicant of the general progress and status of its application; to discuss scientific, policy, and other issues that arise during the review process; and to discuss what further steps need to be taken by the applicant before the application can be approved. An applicant shall direct a request for a meeting to the Director of the primary review division. FDA will make every attempt to grant a request for a meeting that involves important issues and that can be scheduled at a mutually convenient time. However, a "drop-in" visit (i.e., an unannounced and unscheduled visit by a company representative) is strongly discouraged except for an extremely urgent matter, such as to discuss an important new safety issue.

§ 514.103 Dispute resolution.

(a) *General.* FDA is committed to resolving differences between an applicant and an FDA reviewing division with respect to a technical requirement in an application as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative or procedural issue.* When an administrative or procedural dispute occurs, the applicant shall first attempt to resolve the matter with the primary review division beginning with the primary reviewer. If resolution is not achieved at the division level, the applicant may discuss the matter with the Associate Director for New Animal Drug Evaluation, who will investigate the matter and facilitate a timely and equitable resolution. Examples of appropriate issues to discuss with the Associate Director include difficulty in scheduling a meeting, obtaining a timely reply to an inquiry, and obtaining timely completion of a pending review.

(c) *Scientific or veterinary medical issue.* (1) Because any major scientific or veterinary medical issue is normally communicated to an applicant in an approvable or not approvable letter pursuant to § 514.110 or § 514.120, respectively, the conferences described in § 514.102(c) are intended to provide a forum earlier in the review process for discussing and resolving, if possible, a scientific or veterinary medical issue on which the applicant disagrees with FDA.

(2) If, following the meetings described in § 514.102(c), the applicant and the reviewing division conclude that an impasse exists, the applicant may appeal a decision made by the reviewing division on an issue of science or veterinary medicine. Details on the appeals procedure are contained in CVM Policy and Procedures Manual, which is publicly available.

§ 514.104 Drug with potential for abuse.

FDA will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 811(f)) when an application is submitted for an animal drug that appears to have an abuse potential.

§ 514.105 Approval of an application.

(a) FDA will approve an application described under §§ 514.50, 514.58, or § 514.70(b) and send the applicant an approval letter if none of the grounds specified in section 512(d) of the act or in § 514.125 for refusing to approve the application applies.

(1) New animal drug product in finished dosage form or a Category I Type A medicated article that is not to be mixed with a Category II Type A medicated article: The date of approval of the application is the date of FDA's approval letter. A new animal drug product may not be marketed until an approval letter for the product is issued. Notice of approval will be published as a regulation in the **Federal Register** pursuant to section 512(i) of the act.

(2) Category II Type A medicated article: Approval of an application is effective upon publication in the **Federal Register** of a regulation published pursuant to section 512(i) of the act. The date of approval of the application is the date of publication of the regulation. The article may not be marketed until such a regulation has been published.

(b) FDA will approve an application and issue to the applicant an approval letter (rather than an approvable letter under § 514.110) on the basis of draft labeling, if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an MFA or a supplemental MFA submitted under § 514.51 or § 514.75, respectively, within 90 days after the date of receipt, or additional time as mutually agreed, if FDA determines that none of the grounds for refusing approval specified in section 512(m)(3) of the act applies. FDA will notify the applicant that the application has been approved by signing and mailing to the applicant the original copy of the Form FDA 1900.

§ 514.106 Categories of supplemental applications.

(a) FDA will assign a supplement to its proper category to ensure appropriate processing of the application.

(b)(1) *Category I.* Supplements that ordinarily do not require a reevaluation of any of the safety or effectiveness data in the parent application. Category I supplements include the following:

(i) A corporate change that alters the identity or address of the sponsor of the application.

(ii) The sale, purchase, or construction of manufacturing facilities.

(iii) The sale or purchase of an application.

(iv) A change in container, container style, shape, size, or components.

(v) A change in approved labeling (color, style, format, addition, deletion, or revision of certain statements, e.g., trade name, storage, expiration dates).

(vi) A change in promotional material for a prescription drug not exempted by § 514.70(c)(10), (c)(11), or (d)(2).

(vii) Changes in manufacturing processes that do not alter the method of manufacture or change the final dosage form.

(viii) A change in bulk drug shipments.

(ix) A change in an analytical method or control procedures that do not alter the approved standards.

(x) A change in an expiration date.

(xi) Addition of an alternate manufacturer, repackager, or relabeler of the drug product.

(xii) Addition of an alternate supplier of the new drug substance.

(xiii) A change permitted in advance of approval as listed in § 514.70(d)(2).

(xiv) Changes not requiring prior approval which are listed under § 514.70(c)(10) and (c)(11) when submitted as a supplement.

(2) *Category II.* Supplements that may require a reevaluation of certain safety or effectiveness data in the parent application. Category II supplements include the following:

(i) A change in the active ingredient concentration or composition of the final product.

(ii) A change in quality, purity, strength, or identity specifications of the active or inactive ingredients.

(iii) A change in dose (amount of drug administered per dose).

(iv) A change in the treatment regimen (schedule of dosing).

(v) Addition of a new therapeutic claim to the approved uses of the product.

(vi) Addition of a new or revised animal production claim.

(vii) Addition of a new species.

(viii) A change in the prescription or over-the-counter status of a drug product.

(ix) A change in statements regarding side effects, warnings, precautions, and contraindications, except the addition of approved statements to container, package, and promotional labeling, and prescription drug advertising.

(x) A change in the drug withdrawal period prior to slaughter or in the milk discard time.

(xi) A change in the tolerance for drug residues.

(xii) A change in analytical methods for drug residues.

(xiii) A revised method of synthesis or fermentation of the new drug substance.

(xiv) Updating or changes in the manufacturing process of the new drug substance and/or final dosage form (other than a change in equipment that does not alter the method of manufacture of a new animal drug, or a

change from one commercial batch size to another without any change in manufacturing procedure), or changes in the methods, facilities, or controls used for the manufacture, processing, packaging, or holding of the new animal drug (other than use of an establishment not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

§ 514.107 Foreign data.

(a) *General.* The acceptance of foreign data in an application generally is described in the CVM Policy and Procedures Manual, which is publicly available.

(b) *As sole basis for marketing approval.* An application based solely on foreign clinical data may be approved if:

(1) The foreign data are applicable to the treatment of the U.S. animal population and U.S. veterinary medical practice;

(2) The studies have been conducted by qualified clinical investigators of recognized competence; and

(3) The data may be considered valid without the need for an FDA on-site inspection or, if FDA determines that such an inspection is necessary, FDA can validate the data through an on-site inspection or other appropriate means. Failure of an application to meet all these criteria will result in the application not being approvable based on the foreign data alone.

(c) *Consultation between FDA and an applicant.* An applicant is encouraged to meet with agency officials prior to submitting an application based solely on foreign data.

§ 514.110 Approvable letter to the applicant.

At the end of the review period, FDA may inform an applicant that the application is basically approvable provided certain issues are resolved. FDA will send the applicant an approvable letter if the application substantially meets the requirements of this part and the agency believes that it can approve the application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are met. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. Within 60 days after the date of an approvable letter, the applicant shall:

(a) Amend the application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to provide time for the agency to review the amendment.

(b) Withdraw the application. FDA will deem the applicant's failure to respond within 60 days to an approvable letter to be a withdrawal of the application by the applicant as provided in § 514.65. Such a withdrawal is without prejudice to refiling.

(c) Ask CVM to provide the applicant with a written notice of opportunity for hearing on a proposal to refuse approval of the application under section 512(d) of the act or § 514.125. The applicant shall submit the request to the Division of Voluntary Compliance and Hearings Development (HFV–240). Within 60 days of the date of the applicant's request, or within a different time period to which CVM and the applicant agree, CVM will either approve the application under § 514.105 or refuse to approve the application under section 512(d) of the act or § 514.125 and give the applicant written notice of opportunity for a hearing under § 514.200 and section 512(c)(2) of the act on a proposal to refuse approval of the application on one or more of the grounds specified in section 512(d) of the act or § 514.125.

(d) Notify FDA in writing that the applicant agrees to an extension of the review period under section 512(c) of the act so that the applicant can determine whether to respond further under paragraph (a), (b), or (c) of this section. The applicant's written notification is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will deem the applicant's failure to respond further within the extended review period to be a withdrawal of the application by the applicant as provided in § 514.65. Such a withdrawal is without prejudice to refiling.

§ 514.120 Not approvable letter to the applicant.

FDA will send the applicant a not approvable letter if FDA believes that the application may not be approved for one of the reasons given in section 512(d) of the act or § 514.125. The not approvable letter will describe the deficiencies in the application. Within 60 days after the date of the not approvable letter, the applicant shall:

(a) Amend the application or notify FDA of an intent to file an amendment under § 514.60. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under § 514.100.

(b) Withdraw the application. FDA will deem the applicant's failure to respond within 60 days to a not approvable letter to be a withdrawal of the application by the applicant as provided in § 514.65. Such a withdrawal is without prejudice to refiling.

(c) Ask CVM to provide the applicant with a written notice of opportunity for a hearing on a proposal to refuse approval of the application under section 512(d) of act or § 514.125. The applicant shall submit the request to the Division of Voluntary Compliance and Hearings Development (HFV–240). Within 60 days of the date of the applicant's request, or within a different time period to which FDA and the applicant agree, CVM will either approve the application under § 514.105 or refuse to approve the application under section 512(d) of the act or § 514.125 and give the applicant written notice of opportunity for a hearing under § 514.200 and section 512(c)(2) of the act on a proposal to refuse approval of the application on one or more of the grounds specified in section 512(d) of the act or § 514.125.

(d) Notify FDA in writing that the applicant agrees to an extension of the review period under section 512(c) of the act and § 514.100(a) so that the applicant can determine whether to respond further under paragraphs (a), (b), or (c) of this section. The applicant's written notification is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will deem the applicant's failure to respond further within the extended review period to be a withdrawal of the application by the applicant as provided in § 514.65. Such a withdrawal is without prejudice to refiling.

§ 514.125 Refusal to approve an application.

(a) CVM will propose to refuse to approve an application and give the applicant written notice of an opportunity for a hearing under § 514.200 on a proposal to refuse approval of the application under section 512(d) of the act or § 514.125 if:

(1) FDA sends the applicant an approvable or a not approvable letter under 514.110 or 514.122; and

(2) The applicant within 60 days of the date of receipt of the letter asks CVM to give the applicant written notice of an opportunity for a hearing on a proposal to refuse approval of the application under section 512(d) of the act or § 514.125; and

(3) FDA finds that any of the reasons given in paragraph (b) of this section apply.

(b) FDA will refuse to approve an application for any of the following reasons:

(1) FDA has determined that any of the grounds for refusing approval specified in section 512(d)(1)(A) through (I) of the act apply.

(2) The application fails to include an appropriate proposed tolerance for residues in edible products derived from an animal or a proposed withdrawal period or other proposed restrictions for use of the animal drug, if any tolerance or withdrawal period or other restrictions for use are required in order to ensure that the edible products derived from an animal treated with such drug will be safe.

(3) In the case of a combination new animal drug product, there is a lack of substantial evidence demonstrating that each component designated as active makes a contribution to the effect in the manner claimed or suggested in the labeling. If in the absence of express labeling claims of advantages for the product, the product purports to be better than either component alone and there is a lack of substantial evidence demonstrating that purported effectiveness.

(4) The conditions of use prescribed, recommended, or suggested in the proposed labeling are not reasonably certain to be followed in practice.

(5) The application does not contain an adequate environmental assessment under § 25.31 of this chapter or sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

(6) The application contains an untrue statement of a material fact.

(7) The applicant's proposed labeling of a new animal drug product does not comply with the requirements for labels and labeling in Part 201 of this chapter.

(8) The applicant fails to correct a deficiency given in FDA's letter explaining a refusal to file the application under § 514.101(d).

(9) The new animal drug product will be manufactured or processed in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and part 207 of this chapter.

(10) The applicant does not permit a duly designated officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities and procedures or refuses to permit access to, or copying or verification of, any records relevant to the application.

(11) The methods to be used in, and the facilities and procedures used for the manufacture, processing, controls, packing, or holding of the animal drug substance or the new animal drug product do not comply with the relevant current good manufacturing practice regulations in parts 210, 211, 225, or 226 of this chapter.

(12) The application does not contain an adequate justification of the omission of a report of any investigation of the animal drug product sponsored by the applicant, or an adequate justification of the omission of other information about the animal drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(13) A nonclinical study that is described in the application and that is essential to show that the new animal drug product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice (GLP) regulations in Part 58 of this chapter and no justification for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the GLP regulations do not support the validity of the study.

(14) The applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

§ 514.126 Adequate and well-controlled studies.

(a) The purpose of conducting a clinical (field) investigation of a new animal drug product is to distinguish the effect of the product from other influences, such as a spontaneous change in the course of the disease or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. FDA considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of section 512 of the act. Reports of adequate and well-controlled investigations, including clinical (field) investigations, provide the basis for determining whether there is "substantial evidence" to support the claims of effectiveness for a new animal drug. Therefore, the study report is required to provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results. In addition, the protocol contains a description of the proposed methods of analysis, and the study report contains a description of the methods of analysis ultimately used. If the protocol does not contain a description of the proposed methods of analysis, the study report describes how the methods used were selected.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of animal drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. Generally, four types of control are recognized:

(i) *Placebo concurrent control.* The test animal drug is compared with an inactive preparation designed to resemble the test animal drug as far as possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control, and usually includes randomization and blinding of investigators.

(ii) *No treatment concurrent control.* Where objective measurements of effectiveness are available and placebo effect is negligible, the test new animal drug product is compared with no treatment. No treatment concurrent control trials usually include randomization.

(iii) *Active treatment concurrent control.* The test new animal drug product is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the well-being of the animal. An active treatment study may include additional treatment groups, however, such as a placebo control, when necessary to determine the effectiveness of the product. Active

treatment trials usually include randomization and blinding of investigators. If the intent of the trial is to show similarity of the test and control animal drugs, the report of the study should assess the ability of the study to have detected a difference between treatments. Similarity of the test new animal drug product and active control can mean either that both animal drugs were effective or that neither was effective. The analysis of the study explains why the animal drugs should be considered effective in the study, for example, by reference to results in previous controlled studies of the active control animal drug.

(iv) *Historical control.* The results of treatment with the test new animal drug product are compared with experience historically derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable individual animals or animal populations. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, leukemia or tetanus) and studies of diseases with signs and symptoms of predictable duration or severity (some forms of parasitism, bovine hypocalcemia, canine eclampsia).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis or treatment is directed.

(4) The method of assigning subjects to treatment and control groups minimizes bias and is intended to ensure comparability of the groups with respect to pertinent variables such as breed, age, sex, severity of disease, duration of disease, and use of animal drugs or therapy other than the test animal drug. The protocol for the study and the report of its results describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification. When the effect of variables is accounted for by an appropriate design, and when, within the same animal, effects due to the test animal drug can be obtained free of the effects of such variables, the same animal may be used for both the test new animal drug product and the control using the controls set forth in paragraph (b)(2)(i), (b)(2)(ii), or (b)(2)(iii) of this section.

(5) Adequate measures are taken to minimize bias on the part of the observers and analysts of the data. The protocol and report of the study describe the procedures, such as blinding, used to minimize bias.

(6) The methods of assessment of the animals' response are well-defined and reliable. The protocol for the study and the report of results explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the test new animal drug product. The report of the study describes the results and the analytical methods used to evaluate them, including when necessary any appropriate statistical methods. The analysis assesses, among other things, the comparability of test and control groups with respect to pertinent variables, and the effects of any interim data analyses performed.

(c) The Director of the Center for Veterinary Medicine may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study, provided the clinical investigation so conducted will yield, or has yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested under § 514.90. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to show why the clinical investigation so conducted will yield, or has yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) For an investigation to be considered adequate for approval of a new animal drug product, the test drug product is required to be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. When carefully conducted and documented, such studies may provide corroborative support of adequate and well-controlled studies regarding effectiveness and may yield valuable data regarding the safety of the test animal drug. Such studies will be considered on their merits in the context of the principles listed in this section, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

§ 514.129 Incomplete application for an animal feed bearing or containing a new animal drug.

When a medicated feed application has been found incomplete due to deficiencies or inaccuracies in the information required in § 514.51, the application shall be considered withdrawn on the date of issuance of the letter citing the deficiencies or inadequacies contained in the application, unless within 30 days the applicant requests a notice of opportunity for a hearing. Such a withdrawal is without prejudice to refiling.

§ 514.150 Withdrawal of approval of an application.

(a) CVM will notify the applicant and afford an opportunity for a hearing on a proposal to withdraw approval of an application approved pursuant to section 512(c) or (m)(2) of the act under section 512(e)(1) or (m)(4)(A) of the act and under the procedures in § 514.200, if any of the following apply:

(1) The Secretary of Health and Human Services has suspended the approval of the application for a new animal drug product or an animal feed bearing or containing a new animal drug on a finding that there is an imminent hazard to the health of man or of the animals for which such drug product or such animal feed is intended. CVM will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) CVM has determined that any of the grounds for withdrawing approval specified in section 512(e)(1) (A) through (E) or section 512(m)(4)(A) (i) through (ii) of the act apply.

(3) CVM has determined under section 512(e)(1)(B) of the act that new evidence of scientific progress shows that the data supporting an NADA no longer constitute adequate tests by all methods

reasonably applicable to a determination of safety.

(4) CVM has determined under section 512(e)(1)(B) of the act that new evidence shows that labeled conditions including indications for use of the new animal drug have not been followed or are not reasonably certain to be followed in practice.

(b) CVM may notify the applicant and afford an opportunity for a hearing on a proposal to withdraw approval of the application approved pursuant to section 512(c) or (m)(2) of the act, under section 512(e)(2) or (m)(4)(B) of the act and under the procedures in § 514.200, if any of the following apply:

(1) CVM has determined that any of the grounds for withdrawing approval specified in section 512 (e)(2)(A) through (e)(2)(C) or section 512 (m)(4)(B)(i) through (m)(4)(B)(iii) of the act apply.

(2) The applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(3) In the case of an application approved pursuant to section 512(c) of the act, CVM finds:

(i) That the application does not contain an adequate justification of the omission of a report of any investigation of the new animal drug product sponsored by the applicant, or an adequate justification of the omission of other information about the new animal drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(ii) That any nonclinical laboratory study that is described in the application and that is essential to show that the new animal drug product is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice (GLP) regulations in Part 58 of this chapter and no justification for the noncompliance was provided or, if it were, the differences between the practices used in conducting the study and the GLP regulations do not support the validity of the study.

(iii) The applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(c) CVM will withdraw approval of an application approved pursuant to section 512 (c) or (m)(2) of the act if the applicant requests withdrawal because the new animal drug product or the animal feed bearing or containing a new animal drug and subject to the application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section applies to the drug product or animal feed. CVM will consider a written request for withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a new animal drug product or animal feed bearing or containing a new animal drug is sufficiently serious that the drug product or animal feed should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to voluntarily remove the product from the market. If the applicant agrees, FDA will not make a finding under paragraph (b) of this section, but will withdraw approval of the application in a notice published in the **Federal Register** that contains a brief summary of the reasons for withdrawal.

§ 514.152 Notice of withdrawal of approval of an application for a new animal drug.

If FDA withdraws approval of an application for a new animal drug product approved pursuant to section 512(c) of the act, FDA will publish in the **Federal Register** a notice announcing the withdrawal of approval and a final rule removing that portion of the regulations promulgated under section 512(i) of the act reflecting the approval. A medicated feed application approved pursuant to section 512(m)(2) of the act shall be deemed to be withdrawn upon publication of the final rule removing the corresponding regulation.

§ 514.160 Approval or reinstatement of an application for which approval was refused, suspended, or withdrawn.

Upon FDA's own initiative or upon request of an applicant, FDA may, on the basis of new information, approve an application for which it had refused, suspended, or withdrawn approval. CVM will publish in the **Federal Register** pursuant to section 512(i) of the act a regulation reflecting the approval.

§ 514.170 Adulteration and misbranding of an approved animal drug.

Any animal drug, including a new animal drug product FDA approves under section 512 of the act and this part, is subject to all the adulteration and misbranding provisions in sections 501 and 502 of the act. FDA is authorized to regulate an approved new animal drug product by proceedings for the enforcement, or to restrain violations, of the act by and in the name of the United States and by regulations issued through informal rulemaking under sections 501, 502, and 701(a) of the act.

Subpart D—Hearing Procedures for New Animal Drugs

§ 514.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* As provided herein and in part 12 of this chapter, CVM will give the applicant notice of opportunity for a hearing on a proposal to refuse approval of an application or to withdraw the approval of an application. The notice will state the reasons for the action and the proposed grounds for the order.

(1) The notice may simply summarize in a general way the information resulting in the notice or refer to specific requirements in the statute and regulations with which there is a lack of compliance, or provide a detailed description and analysis of the specific facts resulting in the notice.

(2) CVM will publish the notice in the **Federal Register** and will state that the applicant, who wishes to participate in a hearing, has 30 days after the date of publication of the notice to file a written notice of participation and request for hearing. If an applicant fails to file a written notice of participation and request for hearing within 30 days, the applicant waives the opportunity for a hearing.

(b) *Notice to applicant.* FDA will provide a copy of the notice of opportunity for a hearing to any firm or person who has submitted an application, by delivering the notice in person or sending it by registered or certified mail to the last address shown in the application and by publication of the notice in the **Federal Register**. However, it is the responsibility of every manufacturer of an animal drug product to review every notice of opportunity for a hearing published in the **Federal Register** to determine whether it covers any animal drug product that firm or person manufactures.

(c) *Notice of participation and request for a hearing, and submission of studies and comments.* (1) The applicant who wishes to participate in a hearing shall file with the Dockets Management Branch (HFA–305), Food and Drug

Administration, 12420 Parklawn Dr., Rockville, MD 20857:

(i) Within 30 days after the date of publication of the notice, a written notice of participation and request for a hearing, and

(ii) Within 60 days after the date of publication of the notice, unless a different period of time is specified in the notice, the studies on which the applicant relies to justify a hearing as specified in paragraph (d) of this section.

The applicant may incorporate in its submission in support of the request for hearing the raw data underlying a study if the data were previously submitted to FDA as part of an application or other report. If an applicant fails to file any studies to justify a hearing as specified in paragraph (d) of this section, the applicant waives the opportunity for a hearing.

(2) FDA will not consider data or analyses submitted after 60 days in determining whether a hearing is warranted unless they are derived from adequate and well-controlled studies begun before the date of the notice of opportunity for a hearing and the results of the studies were not available within 60 days after the date of publication of the notice. Nevertheless, FDA may consider other studies on the basis of a showing by the applicant requesting a hearing of inadvertent omission and hardship. The applicant requesting a hearing shall list in the request for hearing all studies in progress, the results of which the applicant intends to submit later in support of the request for a hearing. The applicant shall submit under paragraph (c)(1)(ii) of this section a copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies.

(d) *Supporting information.* The applicant requesting a hearing is required to submit under paragraph (c)(1)(ii) of this section the studies (including all protocols and underlying raw data) on which the applicant relies to justify a hearing with respect to the new animal drug product, except that an applicant who requests a hearing on the refusal to approve an application is not required to submit additional studies and analyses if the studies upon which the applicant relies have been submitted in the application and in the format and containing the summaries required under § 514.50.

(1) If the grounds for CVM's proposed action concern the effectiveness of the new animal drug product, each request for hearing is required to be supported only by adequate and well-controlled clinical studies meeting each of the requirements of § 514.126 or by other studies not meeting those requirements but for which a waiver has been previously granted under § 514.126. Each applicant requesting a hearing shall submit all adequate and well-controlled clinical studies on the animal drug product, including any unfavorable analyses, views, or judgments with respect to the studies. No other data, information, or studies may be submitted.

(2) The submission is required to include a factual analysis of all the studies submitted. If the grounds for CVM's proposed action concern the effectiveness of the new animal drug product, the analysis is required to specify how each study accords, on a point-by-point basis, with each criterion required for an adequate and well-controlled clinical investigation established under § 514.126, or the study is required to be accompanied by an appropriate waiver previously granted by FDA. If the study concerns a new animal drug product or dosage form or conditions of use or mode of administration other than the one in question, that fact is required to be clearly stated. Any study conducted on the final marketed form of the new animal drug product is required to be clearly identified.

(3) Each applicant requesting a hearing shall submit an analysis of the data upon which the applicant relies, except that the required information relating either to safety or to effectiveness may be omitted if the notice of opportunity for a hearing does not raise any issue with respect to that aspect of the new animal drug product. FDA can most efficiently consider submissions made in the following format.

I. Safety data.
  A. Animal safety data.
  1. Controlled studies.
  2. Partially controlled or uncontrolled studies.
  3. Documented case reports.
  4. Pertinent marketing experience that may influence a determination about the safety of the animal drug product.
  B. Human safety data.
  1. Toxicology.
  2. Residue depletion and assay methods.

II. Effectiveness data.
  Controlled studies, with an analysis showing clearly how each study satisfies, on a point-by-point basis, each of the requirements of § 514.126.

III. A summary of the data and views setting forth the rationale and purpose for the animal drug and its ingredients and the scientific basis for the conclusion that the new animal drug product and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted or the requirements of any element of § 514.126 have not been fully met, that fact is required to be stated clearly and a waiver previously granted by FDA under § 514.126 is required to be submitted.

IV. A statement signed by the person responsible for such submission that it includes in full, or incorporates as provided in § 514.200(c)(2), all studies and information specified in § 514.200(d).

(**Warning:** A willfully false statement is a criminal offense (18 U.S.C. 1001).)

(e) *Separation of functions.* Separation of functions commences upon receipt of a request for hearing. CVM will prepare an analysis of the request and a proposed order ruling on the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response under paragraph (g) of this section will be submitted to the Office of the Commissioner of Food and Drugs for review and decision. When CVM recommends denial of a hearing on all issues on which a hearing is requested, no representative of CVM will participate or advise in the review and decision by the Commissioner. When CVM recommends that a hearing be granted on one or more issues on which a hearing is requested, separation of functions terminates as to those issues, and representatives of CVM may participate or advise in the review and decision by the Commissioner. The Commissioner may modify the text of the issues, but may not deny a hearing on those issues. Separation of functions continues with respect to issues on which CVM has recommended denial of a hearing. The Commissioner will neither evaluate nor rule on CVM's recommendation on such issues and such issues will not be included in the notice of hearing. Participants in the hearing may make a motion to the administrative law judge for the inclusion of any such issue in the hearing. The ruling on such a motion is subject to review in accordance with § 12.35(b) of this chapter. Failure to so move constitutes a waiver of the right to a hearing on such an issue. Separation of functions on all issues resumes upon issuance of a notice of hearing. The Office of the General Counsel, Department of Health and Human Services, will observe the same separation of functions.

(f) *Summary judgment.* A person who requests a hearing may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to a particular new animal drug product specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 514.126 showing effectiveness have been identified. Any order entering summary judgment is required to set forth the Commissioner's findings and conclusions in detail and is required to specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(2) When following a general notice of opportunity for a hearing (as defined in paragraph (a)(1) of this section) CVM concludes that summary judgment against a person requesting a hearing should be considered, CVM may serve upon the person requesting a hearing, by registered or certified mail, a proposed order denying a hearing. This person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) When following a general or specific notice of opportunity for a hearing a person requesting a hearing submits data or information of a type required by the statute and regulations, and CVM concludes that summary judgment against the person should be considered, CVM will serve upon the person by registered or certified mail a proposed order denying a hearing. The person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted show that the grounds cited in the notice are not valid, for example, that substantial evidence of effectiveness exists, the Commissioner will enter summary judgment for the person requesting the hearing, and rescind the notice of opportunity for a hearing.

(5) If the Commissioner grants a hearing, it will begin within 90 days after expiration of the time for requesting the hearing unless the parties otherwise agree in the case of refusal of approval, and as soon as practicable in the case of withdrawal of approval.

(6) The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest.

(7) A request for a hearing, and any subsequent grant or denial of a hearing, applies only to the new animal drug products named in such documents.

(g) *Final action.* CVM and the Commissioner, respectively, will issue a notice refusing or withdrawing approval of, and declaring unlawful, all new animal drug products subject to a notice of opportunity for a hearing for which an opportunity for a hearing is waived or for which a hearing is denied. The Commissioner may defer or stay the action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

§ 514.201 Procedure for hearings.

Parts 10 through 16 of this chapter apply to hearings relating to new animal drugs and animal feeds bearing or containing new animal drugs under sections 512 (d), (e), (m)(3), (m)(4), and (n) of the act.

§ 514.235 Judicial review.

(a) The Commissioner will certify the transcript and record. In any case in which the Commissioner enters an order without a hearing under § 514.200(f), the record certified by the Commissioner is required to include the requests for hearing together with the data and information submitted and the Commissioner's findings and conclusions.

(b) An applicant may seek judicial review of an order refusing or withdrawing approval of a new animal drug application, whether or not a hearing has been held, in a U.S. Court of Appeals under sections 505(h) and 512(h) of the act.

Subpart E—[Reserved]

Subpart F—Miscellaneous Provisions

§ 514.410 Imports and exports of a new animal drug.

(a) *Imports.* (1) A new animal drug product may be imported into the United States only if:

(i) It is the subject of an application approved under this part; or

(ii) It complies with the regulations pertaining to investigational new animal drugs under part 511 of this chapter.

(2) An animal drug substance intended for use in the manufacture, processing, or repackaging of a new animal drug may be imported into the United States only if it complies with § 201.122 of this chapter pertaining to shipments of animal drug substances in domestic commerce.

(b) *Exports.* (1) A new animal drug product may be exported only if:

(i) It is the subject of an application approved under this part;

(ii) It complies with the regulations pertaining to investigational new animal drugs under part 511 of this chapter; or

(iii) It is the subject of an export application approved under section 802 of the act.

(2) A new animal drug substance that is covered by an application approved under this part for use in the manufacture of an approved new animal drug product may be exported by the applicant or any person listed as a supplier in the approved application, provided the animal drug substance intended for export meets the specifications of, and is shipped with a copy of the labeling required for, the approved new animal drug product.

§ 514.420 Drug master file.

(a) A drug master file (DMF) is a submission of information to FDA by a person (the holder of a DMF) who intends it to be used for one of the following purposes:

(1) To permit the holder to incorporate the information in an investigational new animal drug (INAD) notice as described under part 511 of this chapter or an application as defined in § 514.3.

(2) To permit the holder to authorize another person to rely on the information to support a submission to FDA without the holder having to disclose information in the DMF to the other person.

(b) FDA does not independently review, approve or disapprove a DMF. FDA reviews the information, as authorized, only in conjunction with a review of INAD notices as described under part 511 of this chapter,

applications as defined in § 514.3, or another DMF.

(c) FDA has prepared and made available a guideline that provides information about how to prepare a well organized DMF.

(d) Two copies of a DMF are required to be submitted. A DMF may contain information of the kind required for any submission to the agency, including information about the following:

(1) Facilities and operating procedures used in the manufacture, packaging, labeling and a control of an animal drug substance or animal drug product (Note: Holders of a DMF for foreign establishments shall abide by this requirement);

(2) Components used in the manufacture of an animal drug substance or animal drug product;

(3) Manufacturing instructions;

(4) Packaging materials;

(5) Analytical controls;

(6) Stability program/data;

(7) Analytical method validation information;

(8) Environmental data/information;

(9) Human food safety, preclinical, or clinical data.

(e) All or part of the contents of any DMF may be incorporated or used in support of an INAD notice as described under part 511 of this chapter or an application as defined in § 514.3 if the holder of the DMF provides written authorization to FDA for such use. Each incorporation is required to describe the incorporated material by name, reference number, volume, and page number of the status DMF.

(f) A holder of a DMF shall provide updated data and information on an annual basis to reflect the status of current operations for those files describing any manufacturing operations.

(g) If the holder of a DMF adds, changes, or deletes any information in the file, the holder shall provide written notification to FDA and all other persons authorized to refer to the cited file. Two copies of any addition, change, or deletion of information in the DMF shall be provided to FDA. All copies shall identify the specific file change(s) by reference to a volume number and page.

(h) A list identifying and designating the appropriate information (application number, product name, and designated firm) to which the authorization applies shall be provided on an annual basis.

(i) The public availability of data and information in a DMF, including the availability of data and information in the file to a person authorized to reference the file, is determined under part 20 of this chapter and § 514.430.

§ 514.421 Public master file.

A public master file (PMF) is established by FDA and contains information (other than manufacturing) relative to an animal drug. The public may access the information in a drug master file, because that information is acquired with public funds. The existence of a PMF is made known by a notice published in the **Federal Register**.

§ 514.430 Availability for public disclosure of data and information in an application.

(a) FDA will determine the public availability of any part of an application under this section and part 20 of this chapter. For purposes of this section, the application includes all data and information submitted with or incorporated in the application, including INAD notices as described under part 511, applications as defined in § 514.3, reports under § 514.80, and other submissions, e.g., drug master files under § 514.420. For purposes of this section, safety and effectiveness data include all studies and tests of an animal drug in laboratory animals and the target species and all studies and tests of the animal drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application before an approval letter is sent to the applicant under § 514.105, unless the existence of the application has been previously publicly disclosed or acknowledged. CVM will maintain and make available for public disclosure a list of applications for which FDA has sent an approval letter to the applicant.

(c) If the existence of an unapproved application has not been publicly disclosed or acknowledged, no data or information in the application is available for public disclosure.

(d) If the existence of an application has been publicly disclosed or acknowledged before FDA approves the application, no data or information contained in the application is available for public disclosure before FDA approves the application, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue, for example, for consideration of an issue at an open session of an FDA advisory committee.

(e) After FDA approves an application, the following data and information in the application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist:

(1) All safety and effectiveness data previously disclosed to the public as set forth in § 20.81 of this chapter.

(2) If the approval is for a new animal drug product, a summary or summaries of the safety and effectiveness data and information submitted with or incorporated in the application. The summaries do not constitute the full reports of investigations under section 512 (b)(1) or (b)(2) of the act on which the safety and effectiveness of the product may be approved. The summaries consist of the following:

(i) For an application approved before July 1, 1975, internal agency records that describe safety and effectiveness data and information, for example, a summary of the basis for approval or internal reviews of the data and information, after deletion of the following:

(A) Names and any pertinent information that would identify the investigators.

(B) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an application approved on or after July 1, 1975, a summary of the safety and effectiveness data and information evaluated by CVM during the animal drug approval process. The summary is prepared in one of the following ways:

(A) Before approval of the application, the applicant shall prepare a draft summary which CVM will review and may revise. The draft may be submitted with the application or as an amendment.

(B) CVM may prepare its own summary.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a veterinarian or hospital or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as set forth in § 20.81 of this chapter.

(6) Analytical methods used for regulatory purposes which are shown to fall within the exemption established for trade secrets and confidential

commercial information in § 20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application, under the provisions of part 20 of this chapter.

(f) All safety and effectiveness data and information which have been submitted in an application and which have not previously been disclosed to the public are available to the public, upon request, at the time any one of the following events occurs unless extraordinary circumstances are shown:

(1) No work is being or will be undertaken to have the application approved.

(2) A final determination is made that the application is not approvable and all legal appeals have been exhausted.

(3) Approval of the application is withdrawn and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without the submission of such safety and/or effectiveness data and information.

(g) The following data and information in an application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.61 of this chapter or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61 of this chapter:

(1) Quantitative or semiquantitative batch formulas.

(2) Manufacturing methods and processes, including quality control procedures.

(3) Production, sales distribution, and similar data and information, except that any compilation of that data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(h) The compilations of information specified in § 20.117 of this chapter are available for public disclosure.

§ 514.440 Addresses.

(a) An applicant shall normally submit an application and other correspondence relating to matters covered by this part to the Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, and to the appropriate office identified below:

(1) An application under §§ 514.50, 514.58, 514.60, or 514.70 should be submitted to the Document Control Section (HFV–199). An applicant may obtain binders to contain the application from that office. After FDA has filed an application, the agency will designate a primary review division as provided in § 514.100(a)(1). An amendment, supplement, resubmission, request for waiver, or other correspondence about the application that has been filed should be submitted to the Document Control Section (HFV–199), attention of the primary review division assigned (the file or application number and date of last FDA correspondence should also be identified).

(2) A medicated feed application (Form FDA 1900) under § 514.51 and amendments and supplements under § 514.71 should be submitted to the Division of Animal Feeds (HFV–220).

(3) A request for a notice of opportunity for a hearing under § 514.110 or § 514.120 on a proposal to refuse approval of an application should be submitted to the Division of Voluntary Compliance and Hearings Development (HFV–240).

(4) A request for a copy of the list of guidelines that apply to parts 500 through 599 of this chapter or of a specific guideline should be submitted to the Industry Information Staff (HFV–12).

(5) A periodic report, whether Form FDA 1932, Form FDA 2301, or equivalent, should be submitted to the Division of Surveillance (HFV–210).

(b) [Reserved]

§ 514.445 Guidelines.

(a) FDA prepares and makes available guidelines to help persons comply with requirements in this part. When a guideline is made available under § 10.90(b) of this chapter, the notice of availability of the guideline will so state.

(b) CVM will maintain and make publicly available a list of guidelines that apply to parts 500 through 599 of this chapter. The list will state how a person can obtain a copy ot each guideline.

Editorial Note. This document was received by the Office of Federal Register on December 9, 1991.

Dated: July 1, 1991.

David A. Kessler,

Commissioner of Foods and Drugs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 226, 510, and 514

[Docket No. 88N–0038]

RIN 0905–AA96

Records and Reports Concerning Experience With New Animal Drugs for Which an Approved Application Is In Effect

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the requirements for recordkeeping and reporting of adverse experiences and other information relating to approved new animal drugs and medicated feeds. The kinds of information to be maintained and submitted by the applicant will be defined more clearly. The timing and content of certain reports will be revised to enhance the usefulness of the information. The purpose of these proposed changes is to improve protection of public health, including protection of animals, while also reducing or eliminating unnecessary reporting requirements. These proposed changes are part of a revision of the animal drug regulations. Another proposed rule, published elsewhere in this issue of the Federal Register, would provide for a major revision of the sections in 21 CFR part 514. That proposal concerns regulations affecting new animal drug applications (NADA's) and is known as the "NADA Rewrite."

DATES: Comments by February 18, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, room 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8722.

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I. Introduction

The agency is proposing revisions in the recordkeeping and reporting requirements, including reports of adverse drug experiences, that apply after FDA approves an NADA or medicated feed application (MFA). Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(l)) provides that following approval of an NADA, the applicant shall establish and maintain such records and make such reports to the agency as are prescribed by regulation or order. Section 512(m)(5) of the act establishes similar requirements with respect to an MFA. FDA has promulgated regulations to implement sections 512(l) and 512(m)(5) in 21 CFR 510.300 and 510.301. Upon finalization of this proposed rule, those sections will be redesignated as 21 CFR 514.80, 514.81, and 514.82.

The recordkeeping and reporting requirements enable FDA to monitor the use of a new animal drug or medicated animal feed after approval. Such records and reports are necessary for the agency to determine whether the approval of an application should be withdrawn. FDA must withdraw approval if, among other things, new information shows that the drug or medicated feed is unsafe or ineffective (21 U.S.C. 360b(e) and (m)(4)). FDA may withdraw approval of an application if an applicant fails to establish a system for maintaining required records, fails to maintain records or make reports, or refuses to permit access to, or copying or verification of, its records (21 U.S.C. 360b(e)(2)(A) and (m)(4)(B)(i)).

II. Records and Reports Concerning New Animal Drugs

A. Current Requirements

Section 510.300 *Records and reports concerning experience with new animal drugs for which an approved application is in effect,* requires submission of several types of reports:

1. Immediate Reports (21 CFR 510.300(b)(1)).

Applicants are required to report immediately information about any mixup in a new animal drug or its labeling with another article; any bacteriological or significant physical or other change or deterioration in the new animal drug; and any failure of one or more distributed batches of the new animal drug to meet established specifications.

2. Fifteen-Day Reports (21 CFR 510.300(b)(2)).

Applicants are required to report as soon as possible, but not later than 15 working days after the applicant obtains the information, unexpected side effects, injuries, toxicities, or sensitivity reactions associated with clinical use or studies of a new animal drug, and information about any unusual failure of the animal drug to exhibit its expected pharmacological activity. Applicants are also required to report any increase in the incidence or severity of adverse reactions.

3. Six-Month Reports (21 CFR 510.300(b)(4)).

Within 6 months of approval, and again within a second 6-month period, applicants are required to provide the following information about each new animal drug: (i) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by or reported to the applicant; (ii) experience, investigations, studies, or tests involving the chemical, physical, or other properties of the animal drug; (iii) copies of all labeling and, for prescription animal drugs, advertising; (iv) the quantity of the animal drug distributed; and (v) manufacturing or control changes that do not require a supplemental NADA. However, the applicant is not required to submit information previously reported, for example, in an immediate or 15-day report. In addition, applicants are required to submit samples of promotional labeling at the time of initial dissemination and advertisements for prescription animal drugs at the time of initial publication. Thus, they are not required to submit the same information in the 6-month reports.

4. Annual Reports (21 CFR 510.300(b)(4))

After the two initial 6-month periods, applicants are required to provide annually the information listed in the previous paragraph.

B. Proposed Changes

1. Reports That Would Be Required From Applicants (21 CFR 514.80, 514.81, and 514.82)

The agency proposes to improve the current reporting system by requiring the following types of reports: (i) 3-day "NADA-field alert reports," involving certain product and manufacturing detects; (ii) 15-day "alert reports" for all adverse drug experiences that are both serious and unexpected, as well as for any significant increase in the frequency of serious, expected adverse drug experiences; (iii) periodic adverse drug experience reports for all other adverse drug experiences, as well as product defect information not covered by a 3-day NADA-field alert report, at quarterly intervals for 3 years from the date of approval of the application, and annually thereafter; (iv) annual reports for other information necessary to monitor safety of the animal drug product; and (v) other reports to meet particular needs. The proposed rule also defines key terms including "adverse drug experience," "increased frequency," "serious," "unexpected," "product defect," and "manufacturing defect." For the purpose of the proposed rule, the term "NADA" includes both an abbreviated NADA, and all amendments and supplements.

The proposed reports would closely parallel those required under the revised regulations governing the marketing of new drugs for human use (21 CFR 314.80, 50 FR 7452, February 22, 1985), and would simplify the process for those firms that manufacture both kinds of products. Because of the proposed quarterly reporting requirement for adverse drug experiences, the proposed rule would eliminate the requirement for a 6-month complete report, which is now used to monitor an animal drug's safety in the first year after approval.

a. *Three-day "NADA-field alert reports".* (21 CFR 514.80(d)(1), 514.81(d)(1), 514.82(d)(1)). The "immediate report" would be sent to an FDA district office and its title would be changed to "NADA-field alert report." Product defects that are manufacturing defects would be included in the "immediate report." The proposal defines the terms "product defect" and "manufacturing defect." The latter category includes defects that have a potential for causing significant safety

or effectiveness problems in one or more lots of an animal drug. The proposed rule provides examples of manufacturing defects.

Under the proposal, the requirement for immediate reporting of manufacturing defects would be met if the applicant reported the information to the appropriate FDA district office within 3 working days of the applicant's receipt of that information. FDA recognizes that an applicant may not be able to submit a complete report within that time. The agency believes, however, that these reports, which can assist in the prevention of safety and effectiveness problems from the use of products already in distribution, are important and must be made whether or not the applicant has obtained all the facts regarding the incident giving rise to the report.

b. *Fifteen-day "alert reports".* (21 CFR 514.80(d)(2), 514.81(d)(2), 514.82(d)(2)). Under the proposed rule, FDA would require adverse drug experiences that are both serious and unexpected to be reported within 15 working days of receipt of the information. The 15-day report would be called an "alert report." Applicants would be required to report these experiences as soon as possible, and in any event within 15 days, even if they have not obtained complete information about the experiences. Followups of 15-day alert reports would be required within 15 working days of the applicant's receipt of new information. Additionally, the applicant would be required to review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected, regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 days of determining that a significant increase in frequency exists.

c. *Periodic adverse drug experience reports.* (21 CFR 514.80(d)(3), 514.81(d)(3), 514.82(d)(3)). Under the proposal, applicants would be required to report all adverse drug experiences (other than those already reported under the preceding paragraph) quarterly for 3 years following approval of the application and annually thereafter as part of the annual reports. Quarterly reports would have to be submitted within 30 days of the close of a quarter.

d. *Annual reports.* (21 CFR 514.80(d)(4), 514.81(d)(4), 514.82(d)(4)). Annual reports, to be submitted within 60 days of the anniversary of approval, would include distribution data, labeling, own-label (private label) distribution data, manufacturing or control changes, nonclinical laboratory studies and clinical data, and the adverse drug experience reports mentioned in the previous paragraph.

e. *Other reports* (21 CFR 514.80(d)(5), 514.81(d)(5), 514.82(d)(5)). Other reports would include advertising and promotional labeling, distributor statements and labeling, and special reports.

2. Description of Reports Required From Applicants

Principal changes from the current system that would be brought about by this proposed rule are described in the following paragraphs.

First, the proposal would focus 15-day reporting on adverse drug experiences that are both unexpected and serious, rather than unexpected (regardless of severity) as under the current regulations. FDA believes that this change will allow the agency to concentrate its efforts on those reports that are most significant. Reports of any significant increase in frequency of adverse drug experiences would continue to be required within 15 working days after determining that a significant increase in frequency exists, but such reporting requirement would apply only in the case of serious, expected reactions.

Second, FDA is proposing to revise the periodic reporting requirements so that they, too, focus on the most significant information. Currently, the regulations require, in the first year after approval, a 6-month complete report that contains considerable information in addition to adverse drug experiences. This additional information includes: (1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by or reported to the sponsor; (2) experience, investigations, studies, or tests involving the chemical, physical, or other properties of the drug; (3) copies of all labeling and, for prescription drugs, advertising; (4) the quantity of the drug distributed; and (5) manufacturing or control changes that do not require a supplemental NADA. Under the proposed rule, FDA would require this information (other than adverse drug experiences) to be submitted annually rather than semiannually because the timeliness of FDA's receipt of this information is not as critical as it is for adverse drug experiences. Conversely, however, as with human drugs, FDA is proposing that adverse drug experience information for approved new animal drugs, not required in a 15-day report, be reported to the agency quarterly for the first 3 years after approval and annually thereafter. As noted in the preamble to the revised regulations governing the marketing of new drugs for human use (50 FR 7452 at 7472, February 22, 1985), FDA's experience has shown that serious safety problems with a new drug, if any exist, are likely to be detected during the first 3 years of marketing. FDA believes, therefore, that closer surveillance of new animal drugs during this time period is also warranted through the quarterly reporting mechanism.

The proposed rule would require reports of product defects to be submitted quarterly for 3 years following approval and annually thereafter if not previously reported in the NADA-field alert report as manufacturing defects. The proposal also defines the term "product defect" to mean an observable or measurable deviation in any subunit of a lot of a distributed animal drug product from the acceptance standards specified in the approved application, or from the typical physical and chemical characteristics expected for the animal drug product and its container.

Currently, although the regulations do not contain the term "product defect," they require reports involving chemical, physical, or other properties of the drug (see § 510.300(a)(2)) in addition to the information about product-related problems required in the immediate report. FDA has interpreted the regulations to require reporting of "product defect" information. For example, the title of Form FDA 1932 contains the words "Product Defect Report." Many applicants have routinely submitted product defect information in a 15-day report or in a periodic report if they have not submitted it in an immediate report.

Because product defects can result in adverse effects in the animals in which the animal drugs are used, FDA believes that it is important to clarify the need for reporting such information, and the time within which it is to be reported. Although the time that will be allowed for reporting product defects that are not manufacturing defects will be extended beyond the time by which some sponsors have been submitting the information, FDA believes that the proposed periods will provide adequate protection considering that the kinds of problems that are most likely to cause widespread adverse effects would be reported immediately in the NADA-field alert report.

All adverse drug experience and product defect reports would be submitted on Form FDA 1932, "Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." The content of the annual report would remain

essentially unchanged, but the applicable portion of the regulations has been rewritten in the interest of clarity and simplicity. As noted above, the proposal would delete the requirement of a semiannual report in the first year following approval.

The proposed rule would retain the current reporting requirements for new promotional and advertising materials, i.e., they are to be provided at the time of initial dissemination or publication.

The proposal defines the information covered by proposed § 514.80 to include that which is obtained from foreign as well as domestic sources. The change is for clarification, the agency having historically interpreted the regulations to apply to information from both sources.

FDA is proposing to define the term "adverse drug experience." In addition to adverse effects on treated animals, the term would include adverse effects resulting from human exposure during manufacture, testing, or handling, as well as human exposure during use. This provision would codify the agency's current interpretation. Other terms, e.g., "applicant," which means, in relevant part, any person who owns an approved application, are defined in the proposed NADA Rewrite published elsewhere in this issue of the **Federal Register**, and apply to this proposal also.

Section 510.300 now requires any person whose name appears on the labeling of an approved new animal drug, or who manufactures, processes, packs, or labels it, to keep records and make reports to FDA about the animal drug. Due to the two-step nature of the medicated feed approval system (following approval of an NADA for a Type A medicated article, a medicated feed application must be approved to use the article in the manufacture of a Type B or C medicated feed), each of the approved application holders has an obligation to report to FDA any information relating to the use of its product. In addition, under proposed § 514.80(a), the manufacturer of a Type A medicated article for subsequent manufacture of a Type B and/or Type C medicated feed would be required to report such information that is available to the manufacturer and that is associated with the manufacture, distribution, or use of the medicated feeds derived from that article, whether or not the medicated feed manufacturer may have knowledge of such information and may report the same information as required under proposed § 514.81. This provision would clarify a long-standing agency interpretation of the existing regulation (§ 510.300), and would avoid situations in which neither party reports the information because each thought the other would do so.

Currently, applicants are required to maintain indefinitely the records required by § 510.300. The proposed rule would require records to be retained for 10 years.

Reports submitted to FDA are currently required to be submitted in duplicate. The proposal would require only a single copy of each report with two copies of the required labeling to be submitted with the annual report.

3. Proposed Reporting Requirements for Manufacturers, Packers, Labelers, and Distributors Other Than the Applicant (21 CFR 514.82)

In addition, the agency is proposing a new § 514.82 *Records and reports concerning experience with new animal drugs from manufacturers, packers, labelers, and distributors other than the applicant.* The terms defined in § 514.80 will also be cross referenced in § 514.82. Section 514.82 would require the submission of information concerning adverse experiences and product defects by each manufacturer, packer, labeler, and own-label (private label) distributor of a new animal drug other than the applicant who holds the approval for the animal drug.

Own-label (private label) distributors are currently required to submit drug experience reports. However, the requirement is imposed by the regulation that requires prior approval of supplements for distributors (§ 514.8(a)(6)). FDA is proposing to permit the designation of own-label (private label) distributors to be reported after-the fact in the annual drug experience report. In connection with the changes that it is proposing, the agency emphasizes the importance of the reports required to be submitted by own-label (private label) distributors. Manufacturers that are not applicants are now required, under current good manufacturing practice (CGMP) regulations, to maintain records and reports of the types of information covered by proposed § 514.82. However, the CGMP regulations do not explicitly require such manufacturers to report such information to FDA.

Agency experience has led it to conclude that others in the manufacturing and distribution chain, besides the applicant, should be required to submit drug experience reports. In some instances, e.g., in the case of drugs distributed by own-label (private label) distributors, the veterinarian or other user is unable to determine the name of the applicant from the labeling. The proposed rule would therefore enable the agency to monitor more closely the safety, effectiveness, and manufacture of approved new animal drugs.

III. Other Proposed Changes

The agency is also proposing to remove § 510.301 *Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect* and to incorporate certain portions of the regulations into proposed § 514.81. The proposed changes parallel those for § 510.300. which the agency is proposing to remove and to incorporate certain portions of the regulations into proposed § 514.80. The terms defined in proposed § 514.80 will be cross referenced in proposed § 514.81.

Also, the proposed rule would amend Part 226 *Current good manufacturing practice for Type A medicated articles* (21 CFR part 226) to state explicitly that although the recordkeeping requirements of the CGMP regulations for Type A medicated articles apply to Type A medicated articles in general, those Type A medicated articles for which approved NADA's are in effect are also subject to the requirements of proposed § 514.80. This provision is needed primarily to avoid confusion, because §§ 226.110 and 226.115 establish 2–year record retention requirements for distribution records and complaint files. The records and reports that would be required for Type A medicated articles under § 514.80 are more comprehensive and are to be kept for 10 years under proposed § 514.80.

In summary, the following amendments are proposed: § 510.300 through 510.302 and 510.310 would be removed and certain portions of the regulations would be incorporated into § 514.80 through 514.82. Section 510.310 was established to provide for the one-time submission of updating information on animal drugs marketed prior to the effective date of the Drug Amendments of 1962. This information has been submitted, and, thus, § 510.310 no longer serves any useful purpose. Section 514.82 would also be established to clarify the requirement for submitting certain adverse information to FDA.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(d)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The agency concludes that the proposed rule does not constitute a major rule, as defined in Executive Order 12291. The agency also certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action, and, therefore, that a regulatory flexibility analysis is not needed. The revisions in the reporting requirements are expected to result in savings for the applicant and for the agency. In the proposal, the term "applicant" is limited to the holder of an approved NADA and does not include every firm whose name appears on product labeling, as the regulations currently provide. This change would reduce paperwork requirements because fewer firms would be required to submit periodic (annual) drug experience reports.

The current requirement for adverse drug experience reports to be submitted by own-label (private label) distributors is retained under proposed new § 514.82. The requirement for any firm involved in the manufacturing process other than the applicant or own-label (private label) distributor to report adverse experiences either to FDA or the applicant is a new requirement, but it applies only to a small class of firms that would not routinely be expected to receive such information. Nevertheless, it is clear that any such information they do receive should be reported despite the minor associated paperwork burden. Only one copy of the report would be required. The change in retention requirement for reports and records from an indefinite period to a 10–year period would provide an additional opportunity for savings. The reporting requirements would be simplified and clarified for easier compliance and administration. The proposed changes that would add language to the regulations would, for the most part, merely codify current practices. The proposed uniformity of reporting requirements for animal drugs and human drugs may simplify the process for firms that manufacture both kinds of products. Thus, no added costs are expected.

FDA has not done a formal economic impact analysis or gathered any data on the effects of this proposed rule. Not having a threshold assessment of cost savings, FDA would welcome any comments on this or any aspect of the proposed revised requirements.

VI. Paperwork Reduction Act of 1980

Sections 514.80 (a), (c), and (d), 514.81 (a), (c), and (d), and 514.82 (a), (c), and (d) of this proposed rule contain collection of information requirements. Existing information requirements in §§ 514.80 (a) and (c), 514.81 (a) and (c), and 514.82 (a), (c), and (d) have been approved under OMB control number 0910–0019. The remaining information collections are discussed below.

Title: Records and Reports Concerning Experience With New Animal Drugs for Which an Approved Application is in Effect.

Description: The information requirements contained in this proposed rule would collect information from persons who have received FDA approval of an NADA or medicated feed application. The information will enable FDA to monitor the use of a new animal drug or medicated feed after approval. Such reports are necessary for FDA to determine whether the approval of an application must be withdrawn for safety, effectiveness, or other reasons specified in the act.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	No. of respondents	Annual No. of responses	Average burden per response	Annual burden hours
514.80(d) and 514.81(d)	200	400	0.5	200

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, room 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

VII. Comments

Interested persons may, on or before February 18, 1992 submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 226

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and Recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 226, 510, and 514 be amended as follows:

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

1. The authority citation for 21 CFR part 226 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 374).

2. Section 226.1 is amended by redesignating the existing text as paragraph (a) and by adding a new paragraph (b) to read as follows:

§ 226.1 Current good manufacturing practice.

* * * * *

(b) In addition to the recordkeeping requirements in this part, Type A medicated articles requiring approved new animal drug applications are subject to the recordkeeping requirements in § 514.80 of this chapter.

PART 510—NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.300 [Removed]

4. Section 510.300 *Records and reports concerning experience with new animal drugs for which an approved application is in effect* is removed.

§ 510.301 [Removed]

5. Section 510.301 *Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect* is removed.

§ 510.302 [Removed]

6. Section 510.302 *Reporting forms* is removed.

§ 510.310 [Removed]

7. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* is removed.

PART 514—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW ANIMAL DRUG

8. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 376, 381).

9. Sections 514.80, 514.81, and 514.82 are added to subpart B to read as follows:

§ 514.80 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) *Applicability.* Each applicant shall establish and maintain records and make reports for each of its approved NADA's and abbreviated new animal drug applications (ANADA's), as required under this section to facilitate a determination by FDA whether there may be grounds for invoking section 512(e) of the act to suspend or withdraw approval of an application for a new animal drug, or whether any applicable regulation should be amended or revoked. The applicant shall maintain adequately organized and indexed files containing full reports of all information pertinent to the safety or effectiveness of the new animal drug that has not previously been submitted as part of the application for the drug and that is received or otherwise obtained by the applicant from any source, whether foreign or domestic, and shall report such information, whether from a foreign or a domestic source, as is required by this section. Each manufacturer of an approved Type A medicated article shall report all such information associated with the manufacture, distribution, and use of the Type A medicated article and of any feeds incorporating the approved Type A medicated article, whether or not the medicated feed manufacturer has reported the same information in accordance with the requirements of § 514.81.

(b) *Definitions.* As used in this section:

(1) *Adverse drug experience* means any adverse event associated with the use of an animal drug (or adverse experience in humans associated with exposure during manufacture, testing, handling, or use of the drug), whether or not considered drug-related, including the following:

(i) An adverse event occurring in the course of the use of an animal drug product by a veterinarian or by a livestock producer or other animal owner or caretaker;

(ii) An adverse event occurring from animal drug overdose, whether accidental or intentional;

(iii) An adverse event occurring from animal drug abuse or use of the drug not in accordance with its approved indications or conditions of use;

(iv) An adverse event occurring from animal drug withdrawal; and

(v) Any failure of an animal drug product to produce its expected pharmacological action.

(2) *Increased frequency* means an increase in the rate of reported occurrence of a particular adverse drug experience, e.g., an increase in the number of reports of a particular adverse drug experience after appropriate adjustment for drug exposure.

(3) *New animal drug application (NADA)* includes both an abbreviated NADA, and all amendments and supplements.

(4) *Serious* means an adverse drug experience that is fatal, life-threatening, permanently disabling, requires hospitalization, or involves systemic drug or other intervention.

(5) *Unexpected* means an adverse drug experience that is not listed in the current labeling for the animal drug and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.

(6) *Product defect* means an observable or measurable deviation in any subunit of a lot of a distributed animal drug product from the acceptance standards specified in the approved application, or from the typical physical and chemical characteristics expected for the animal drug product and its container.

(7) *Manufacturing defect* means the manufacturing process is the cause of a product defect which is determined after investigation of a product defect complaint or a routine quality control procedure. A manufacturing defect could affect one or more lots of a product.

(c) *Records to be maintained.* The applicant shall maintain records of all information required by this section for a period of 10 years.

(d) *Reporting requirements.* The applicant shall submit to FDA at the specified times one copy of each of the following reports:

(1) *NADA-field alert report.* The applicant shall submit information on any manufacturing defect to the FDA district office that is responsible for the facility involved within 3 working days from the day that the applicant first becomes aware that a defect may exist. The information may be provided by telephone or other telecommunication means, with prompt written followup. The report and its mailing cover are to be plainly marked: "NADA-field alert report." The following are examples of information required to be reported by this paragraph:

(i) Information concerning any incident that causes the distributed animal drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed animal drug product, or any failure of one or more distributed batches of the animal drug product to meet the specifications established for it in the application.

(2) *Fifteen-day alert reports.* (i) The applicant shall report each serious, unexpected adverse drug experience, regardless of the source of the information, as soon as possible, but in any case within 15 working days of initial receipt of the information. The applicant shall submit the information on Form FDA 1932 (Adverse Reaction, Lack of Effectiveness, Product Defect Report) and shall identify the report as a "15-day alert report."

(ii) The applicant shall promptly investigate all adverse drug experiences that are the subject of 15-day alert reports and shall submit followup reports within 15 working days of receipt of new information. If additional information is sought but not obtained within a reasonable period of time, the applicant may be required to submit a followup report briefly describing the steps taken and the reasons additional information could not be obtained.

(iii) The applicant shall periodically review (at least as often as the periodic

reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected, regardless of source, and report any significant increase in frequency of serious, expected adverse drug experiences as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. Upon written notice, FDA may require that the applicant review the frequency of reports of serious, expected adverse drug experiences at intervals different than the periodic reporting cycle. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results), rather than using Form FDA 1932. Fifteen-day alert reports based on significant increases in frequency are required to be submitted under separate cover and may not be included, except for summary purposes, in a periodic report.

(3) *Periodic adverse drug experience reports.* The applicant shall report each adverse drug experience not already reported under paragraph (d)(2) of this section at quarterly intervals for 3 years from the date of approval and annually thereafter. The applicant shall also report all product defect information, excluding information submitted in conjunction with an NADA-field alert report, within these same time periods. The applicant shall submit the information on Form FDA 1932.

(4) *Annual report.* The applicant shall submit the information listed in paragraphs (d)(4)(i) through (d)(4)(v) of this section, in the order listed, each year within 60 days of the anniversary date of approval of the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2301 (Transmittal of Periodic Reports and Promotional Material for New Animal Drugs) and is required to include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval which ends on the anniversary date. Each annual report is required to contain the following:

(i) *Distribution data.* Information about the quantity of the animal drug product distributed under the approved application, including that for each distributor-labeled product. This information is required to include the total number of units of each size and strength or potency distributed (e.g., 100,000 bottles of 100 5-milligram tablets, 50,000 10-milliliter vials of 5 percent solution), the quantities distributed for domestic use, and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(ii) *Labeling.* Two copies of currently used package labeling, including package inserts (if any), or a representative sample of the package labels, and a summary of any changes in labeling that have been made since the last report, listed by date in the order in which they were implemented, or if there have not been any changes, a statement of that fact.

(iii) *Own-label (private label) distributor data.* If a product manufactured under the conditions of a particular NADA approval is distributed under own-label (private label) distributor agreements, the applicant shall submit a complete list of all such own-label (private label) distributors together with one copy of the label used by each distributor.

(iv) *Manufacturing or controls changes.* A description of the manufacturing or controls changes not requiring a supplemental application under § 514.70(d), listed by date in the order in which they were implemented.

(v) *Nonclinical laboratory studies and clinical data.* (A) Copies of in vitro studies (e.g., mutagenicity) and other nonclinical laboratory studies conducted by or otherwise obtained by the applicant.

(B) Copies of published clinical trials of the animal drug (or abstracts of them) including clinical trials on safety and effectiveness, clinical trials on new uses, and reports of clinical experience pertinent to safety conducted by or otherwise obtained by the applicant. Review articles, papers, and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data are not to be reported; and

(C) Descriptions of, or, if available, prepublication manuscripts relating to, completed clinical trials conducted by or known to the applicant. Supporting information is not to be reported. (A study is considered completed no later than 1 year after it is concluded.)

(vi) *Adverse drug experiences.* Adverse drug experiences required to be reported annually under paragraph (d)(3) of this section. The applicant shall submit the information on Form FDA 1932.

(5) *Other reporting*—(i) *Advertisements and promotional labeling.* The applicant shall submit specimens of mailing pieces and any other labeling, and, if it is a prescription new animal drug, advertising devised for promotion of the animal drug product, at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription animal drug product. Mailing pieces and labeling that are designed to contain samples of an animal drug product are required to be complete, except that the sample of the animal drug product may be omitted. Each submission of promotional material is required to be accompanied by a completed transmittal Form FDA 2301 and is required to include a single copy of the product's current labeling.

(ii) *Distributor statements and labeling.* At the time of initial distribution of an animal drug product manufactured in accordance with the conditions of an approved NADA by an own-label (private label) distributor, the applicant shall submit as a special drug experience report:

(A) Two copies of the distributor labeling. The only changes from the conditions of the approved application permitted in such labeling are a different and suitable proprietary name of the new animal drug (if one is used) and the name and address of the distributor as used on the label and labeling. The name of the distributor shall be accompanied by an appropriate qualifying phrase such as "manufactured for" or "distributed by."

(B) A distributor's statement which shall identify the category of his or her operations (for example, wholesaler, retailer) and state that he or she will distribute the new animal drug only under the labeling provided for in the NADA; that any other labeling or advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling provided for in the application; that he or she will adhere to the reporting requirements of § 514.82; and, if the drug is a prescription new animal drug, that he or she is regularly and lawfully engaged in the distribution or dispensing of prescription animal drugs.

(iii) *Statements of NADA approval status.* The statement "NADA _____, approved by FDA" may be added to the label of a product which is the subject of an approved NADA provided that at the time of addition the applicant submits a drug experience report which meets the following conditions: (A) The drug experience report contains two copies of final printed labeling of each piece of labeling being revised which differ from approved labeling only with respect to the addition of the statement, "NADA _____, approved by FDA."

(B) All labeling for each approved product, including distributor labeling,

should be revised to be consistent as soon as possible.

(C) The statement should appear at the bottom of the front panel of the label on the immediate container and at the bottom of the carton labeling (preferably on the front panel). It should appear at the very top (beginning) or the very bottom (end) of inserts.

(D) In terms of type style, size, color or other means of emphasis, the statement should be no more prominent than the least prominent signal word identifying cautionary information appearing on the label (or the text of such cautionary information if no signal word is used to identify it).

(E) In no event may the statement be placed to obscure or otherwise render less conspicuous any necessary information on labels or labeling.

(iv) *Special reports.* Upon written request, FDA may require that the applicant submit the reports required under this section at different times than those stated.

(e) *General requirements.* (1) An applicant is not to include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to an animal drug for which an applicant holds more than one approved application, the applicant shall submit the report to the application that was approved first. If a report refers to more than one animal drug marketed by an applicant, the applicant shall submit the report to the application for each animal drug listed in the report. The report is required to identify all the applications to which the report applies.

(2) Reports of adverse drug experiences in the published literature are required to be accompanied by a copy of the published articles.

(3) The applicant shall separate and clearly mark reports of adverse drug experiences that occur during a postapproval study from those experiences that are reported spontaneously to the applicant.

(f) *Reporting forms.* Applicants shall submit the information described in this regulation on or accompanied by a Form FDA 1932 or Form FDA 2301 as specifically noted in the regulation except that in lieu of Form FDA 1932 the applicant may submit a computer generated report if the information contained therein and the sequence in which it is presented are equivalent to the information and sequence required by Form FDA 1932. The use of computer generated reports requires approval by FDA prior to use. Forms FDA 1932 and FDA 2301 with instructions for use, may be obtained from Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Completed forms should be sent to the same address.

(g) *Access to records and reports.* The applicant shall upon request from any designated officer or employee of the Department of Health and Human Services, at all reasonable times, permit such officer or employee to have access to and copy and verify any records and reports established and maintained under this section.

(h) *Withdrawal of approval.* If an applicant fails to establish and maintain records and make reports required under this section, or refuses to permit access to, or copying or verification of, such records and reports, FDA may withdraw approval of the application to which they relate.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0019)

§ 514.81 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect.

(a) *Applicability.* Each applicant holding an approved MFA shall establish and maintain records and make reports for each of its approved MFA's as required under this section and under section 512(m)(5) of the act to facilitate a determination by FDA whether there may be grounds for invoking section 512(m)(4) of the act to suspend or withdraw approval of an MFA, or whether any applicable regulation should be amended or revoked. The applicant shall maintain adequately organized and indexed files containing full reports of all information pertinent to safety or effectiveness that has not previously been submitted as part of the MFA and that is received or otherwise obtained by the applicant from any source, whether foreign or domestic, and shall report all such information as is required by this section. Each manufacturer of a medicated feed shall report all such information associated with the manufacture, distribution, and use of the feed whether or not the applicant holding the NADA for the Type A medicated article has reported the same information in accordance with the requirements of § 514.80.

(b) *Definitions.* The definitions included in § 514.80 of this part are applicable to the terms used in this section. The term "adverse drug experience" as defined in § 514.80 shall apply to adverse drug experiences resulting from use of a medicated feed.

(c) *Records to be maintained.* The applicant shall maintain records of all information required by this section for a period of 10 years.

(d) *Reporting requirements.* The applicant shall submit to FDA at the specified times one copy of the following reports:

(1) *MFA-field alert reports.* The applicant shall submit information on any manufacturing defect to the FDA district office that is responsible for the facility involved within 3 working days from the day that the applicant first becomes aware that a defect may exist. The information may be provided by telephone or other telecommunication means, with prompt written followup. The report and its mailing cover are to be plainly marked: "MFA-field alert report." The following are examples of manufacturing defects:

(i) Information concerning any incident that causes the medicated feed or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed medicated feed, or any failure of one or more distributed batches of the product to meet the specifications established for it in the application.

(2) *Fifteen-day alert reports.* (i) The applicant shall report each serious, unexpected adverse drug experience, regardless of the source of the information, as soon as possible, but in any case within 15 working days of initial receipt of the information. The applicant shall submit the information on Form FDA 1932 (Adverse Reaction, Lack of Effectiveness, Product Defect Report) and shall identify the report as a "15-day alert report."

(ii) The applicant shall promptly investigate all adverse drug experiences that are the subject of 15-day alert reports and shall submit followup reports within 15 working days of receipt of new information. If additional information is sought but not obtained within a reasonable period of time, the applicant may be required to submit a followup report briefly describing the steps taken and the reasons additional information could not be obtained.

(3) *Periodic adverse drug experience reports.* The applicant shall report each adverse drug experience not already reported under paragraph (d)(2) of this section at quarterly intervals for 3 years from the date of approval and annually thereafter. The applicant shall also report all product defect information, excluding information submitted in

conjunction with an NADA-field alert report, within these same time periods. The applicant shall submit the information on Form FDA 1932.

(e) *Access to records and reports.* The applicant shall upon request from any designated officer or employee of the Department of Health and Human Services at all reasonable times, permit such officer or employee to have access to and copy and verify any records and reports established and maintained under this section.

(f) *Withdrawal of approval.* If an applicant fails to establish and maintain records and make reports required under this section, or refuses to permit access to, or copying or verification of, such records and reports, FDA may withdraw approval of the application to which they relate.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0019)

§ 514.82 Records and reports concerning experience with new animal drugs from manufacturers, packers, labelers, and distributors other than the applicant.

(a) *Applicability.* For the purpose of this section, a manufacturer, packer, labeler, or own-label (private label) distributor of an approved new animal drug other than the applicant is a nonapplicant. Each nonapplicant shall establish and maintain records and make reports for each approved new animal drug as required under this section to facilitate a determination by FDA whether there may be grounds for invoking section 512(c)(2)(G) or 512(e) of the act to suspend or withdraw approval of an NADA or whether any applicable regulation should be amended or revoked. The nonapplicant shall maintain adequately organized and indexed files containing full reports of all information pertinent to the safety or effectiveness of the new animal drug that is received or otherwise obtained by the nonapplicant from any source, whether foreign or domestic, and shall report all such information, whether from a foreign or a domestic source, as is required by this section.

(b) *Definitions.* The definitions included in § 514.80 of this part are applicable to the terms used in this section.

(c) *Records to be maintained.* The nonapplicant shall maintain records of all information required by this section for a period of 10 years.

(d) *Reporting requirements.* The nonapplicant shall submit to FDA or, alternatively, in the case of 15-day alert reports, to the applicant, at the specified times, one copy of the following reports:

(1) *NADA-field alert reports.* Information on any manufacturing defect shall be submitted to the FDA district office that is responsible for the facility involved within 3 working days from the day that the nonapplicant first becomes aware that a defect may exist. The information may be provided by telephone or other telecommunication means, with prompt written followup. The report and its mailing cover are to be plainly marked: "NADA-field alert report." The following are examples of information required to be reported by this paragraph:

(i) Information concerning any incident that causes the distributed animal drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed animal drug product, or any failure of one or more distributed batches of the animal drug product to meet the specifications established for it in the application.

(2) *Fifteen-day alert reports.* (i) Each serious, unexpected drug experience, regardless of the source of the information, as soon as possible, but in any case within 15 working days of initial receipt of the information. If the nonapplicant elects to report to FDA, the nonapplicant shall submit the information to FDA on Form FDA 1932 (Adverse Reaction, Lack of Effectiveness, Product Defect Report) and shall identify the report as a "15 day alert report." If the nonapplicant elects to report to the applicant rather than to FDA, it shall submit each report to the applicant within 3 working days of its receipt by the nonapplicant, and the applicant shall then comply with the requirements of § 514.80. Under this circumstance, the nonapplicant shall maintain a record of this action. The record shall include:

(A) A copy of the drug experience report.

(B) The date the report was submitted to the nonapplicant.

(C) The date the report was submitted to the applicant.

(D) The name and address of the applicant.

(ii) [Reserved]

(e) *Access to records and reports.* The nonapplicant shall upon request from any designated officer or employee of the Department of Health and Human Services, at all reasonable times, permit such officer or employee to have access to and copy and verify any records and reports established and maintained under this section.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0019)

Editorial Note: This document was received by the Office of the Federal Register on December 9, 1991.

Dated: July 1, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-29778 Filed 12-16-91; 8:45 am]

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federal register

Tuesday
December 17, 1991

Part III

Environmental Protection Agency

40 CFR Part 73

Auctions, Direct Sales, and Independent Power Producers Written Guarantee Regulations and Request for Delegation Proposals To Administer the Auctions and Direct Sale; Rule and Notice

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 73

[FRL-4039-2]

Auctions, Direct Sales, and Independent Power Producers Written Guarantee Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to title IV of the Clean Air Act as amended by Public Law 101-549, the Clean Air Act Amendments of 1990 ("the 1990 Amendments") ("the Act"), the Administrator must promulgate regulations to reduce emissions of sulfur dioxide (SO_2) and nitrogen oxides (NO_x), precursors of acid rain. The regulations promulgated today are part of the Title IV program to reduce SO_2 emissions. The centerpiece of this control program is the allocation of transferable allowances, or authorizations to emit SO_2, which are distributed by the Administrator in limited quantities for existing utility units and which eventually must be held by all utility units to cover their SO_2 emissions. These allowances may be transferred among polluting sources and others, so that market forces may govern their ultimate use and distribution, resulting in the most cost-effective sharing of the emissions control burden. In order to stimulate and support such a market in allowances, and to provide a public source of allowances, particularly to new units for which no allowances are allocated, the Administrator is directed under section 416 of the Act to conduct annual sales and auctions of allowances.

Today, EPA is promulgating the regulations for conducting these sales and auctions, as well as regulations under which certain independent power producers ("IPP") may obtain written guarantees of the availability of allowances and may exercise priority in purchasing allowances through the direct sale.

EFFECTIVE DATE: This rule becomes final effective December 17, 1991.

FOR FURTHER INFORMATION CONTACT: Linda Reidt Critchfield, EPA/OAIAP/Acid Rain Division (ANR-445), 401 M St., SW., Washington, DC 20460 (202) 260-7915.

SUPPLEMENTARY INFORMATION:

I. Background

Acid rain is the accepted term which encompasses a complex set of phenomena that begin with fossil fuel emissions, include the transport and transformation of those emissions through the atmosphere, and end with the effects of those emissions and their resulting transformation products on the environment. Specifically, the burning of fossil fuels, particularly coal and oil, releases emissions of sulfur dioxide (SO_2) and nitrogen oxide (NO_x) into the atmosphere. In the atmosphere, SO_2 and NO_x may undergo various chemical reactions, resulting in the transformation of the emissions into chemical products including sulfates, nitrates, sulfuric acid and nitric acid. These compounds can fall to earth near the source or be transported hundreds of miles. They may be deposited during any stage of their transformation, returning to earth as dry deposition in the form of gases, aerosols, and particles of these emissions and their transformation products in the atmosphere contributes to reduced visibility and is suspected of posing a threat to human health at current levels. The acidic deposition resulting from SO_2 and NO_x emissions and their byproducts damages both ecosystems and man-made materials. Of the approximately 23 million tons of SO_2 and 19 million tons of NO_x emitted annually from all sources in the United States in 1985, about 16 million tons of SO_2 and 7 million tons of NO_x were emitted by electric utilities.

Title IV, which sets forth the acid rain control program of the 1990 Amendments, establishes a national cap on utility SO_2 emissions of 8.95 million tons per year (aside from 530,000 tons of additional emissions authorized for each year between 2000 and 2009). This cap will result in SO_2 emissions reductions of ten million tons from 1980 levels, which will be achieved in two phases. Phase I will begin in 1995 and mainly affects large, high-emitting coal-fired utility plants which are listed specifically in the statute. Phase II will begin in 2000 and affects virtually all utility units with output capacity greater than 25 megawatts, and new utility units of any size. In addition, SO_2 sources not explicitly affected by phase II requirements (e.g., industrial facilities) may opt into the allowance trading program.

The centerpiece of the acid rain control program is an innovative system of marketable allowances. An allowance authorizes the emission of up to one ton of SO_2 in one year. The Act explicitly requires "affected" units (most units in operation prior to passage of the Act) to meet an annual sulfur dioxide emissions tonnage limitation expressed for each unit in the language of title IV itself. At the same time, the Act requires the Administrator to allocate annually for each affected unit allowances to emit sulfur dioxide in a number equal in tons to the unit's statutory emissions limitation requirement. Once allowances are allocated, the Act requires that a unit's total annual SO_2 emissions be less than, or equal to, the number of allowances held for that unit. Allowances may be transferred to and from affected units and to and from any person. Allowances not used for compliance in the year in which they are allocated may be banked for future use. As a result, each unit may meet its SO_2 emissions limitation requirements by the most economically efficient means possible, either by selecting the most efficient method of controlling emissions or by purchasing allowances from other units that can reduce emissions more efficiently. In addition, the marketable value of allowances is expected to create incentives for units to achieve greater reductions than required or to achieve reductions through improved or innovative methods.

To maintain the total emissions cap, the Act requires new units (most units commencing operation after passage of the Act) to obtain allowances from existing allowance holders or through the auctions and sales programs, which are the two methods the Act provides for making allowances available in addition to the statutory allocations.

Because the availability of allowances is crucial to assure both the economic efficiency of the emissions limitation program and the addition of new electric generating capacity, title IV mandates that the Administrator hold yearly auctions and direct sales of allowances for a small portion (2.8 percent) of the total allowances required by the statute to be allocated each year. It also requires the Administrator to provide a written guarantee assuring priority for certain new IPPs in purchasing allowances in the direct sales. The auctions, sales, and IPP guarantee provisions of title IV should provide some certainty that units, including new IPPs, will have a public source of allowances beyond those which are allocated initially for existing units. In addition, the auctions are expected to help signal price information to the allowance market early in the regulatory program.

EPA will sell allowances pursuant to section 416(d) of the Act at a once-a-year public auction, to be held no later than March 31 of each calendar year beginning in 1993. Each auction is required to include allowances in an amount prescribed by statute, and obtained from the Auction Subaccount

of the Special Allowance Reserve, as set forth in section 416(d)(1). It may also include allowances offered for sale by private parties pursuant to section 416(d)(4), as well as allowances that are not sold in the direct sale program under section 416(c). The direct sale will begin on June 1 of each calendar year and continue until all allowances are sold or until the last day on which allowances may be transferred for purposes of compliance (as specified in a separate rulemaking: see 40 CFR part 73). Each allowance will be offered for sale at $1500 (indexed yearly to inflation), a price fixed by the Act. Allowances not sold in an annual direct sale will be added to those auctioned in the following year. A crucial element of the direct sales program is the special priority afforded to certain IPPs. As required by the Act, the Administrator will guarantee these IPPs the right to purchase direct sale allowances before the allowances are offered for sale to others. To qualify for the written guarantee, an IPP must meet certain criteria set forth in the Act and incorporated in this regulation. The proceeds from the auctions and direct sales, and any allowances remaining after their completion, will be distributed on a pro rata basis to those from whose allowance allocation allowances were withheld for purposes of creating the Special Allowance Reserve.

At a future date, EPA will propose and promulgate regulations establishing a Special Reserve of Allowances for the purpose of auctions, direct sales, and the IPP written guarantee. As required by section 416(b), those regulations will specify that the Administrator withhold from original allowance holders 2.8% of the total allowances to be allocated each year from 1995 to 1999 and 2.8% of the basic Phase II allowance allocations beginning in the year 2000. That reserve will comprise a subaccount for auctions of 150,000 allowances annually for phase I and 200,000 allowances annually for phase II and a subaccount for direct sales of 50,000 allowances for phase II. The direct sale reserve will be subject to the IPP guarantee.

The calculations for the pro rata distribution of proceeds from, and any allowances remaining after, the auctions and direct sale will also be included in the rulemaking establishing the Special Allowance Reserve.

Table 1 below summarizes the standard auctions and sales schedule required by section 416.

TABLE 1.—ALLOWANCES OFFERED AT AUCTIONS AND SALES

Year of purchase	Spot sale	Advance sale [1]	Spot auction	Advance auction [1]
1993		25,000	[2] 50,000	100,000
1994		25,000	[2] 50,000	100,000
1995		25,000	50,000	100,000
1996		25,000	150,000	100,000
1997		25,000	150,000	100,000
1998		25,000	150,000	100,000
1999		25,000	150,000	100,000
2000 and after	25,000	25,000	100,000	100,000

[1] Not useable until 7 years after purchase.
[2] Not useable until 1995.

The regulations made final today are to be Subpart E of 40 CFR Part 73. Part 73 governs the allowance system and includes several components, the balance of which are being proposed and promulgated according to the schedule listed below:

TABLE 2.—ALLOWANCE SYSTEM RULE

[40 CFR part 73]

Subpart	Proposed rule (date published)	Final rule (target date for publication)
A: Background	December, 1991.	May, 1992.
B: Allocation	March, 1991	December, 1992.
C: Tracking	December, 1991.	May, 1992.
D: Transfers	December, 1991.	May, 1992.
E: Auction and sales.	May 23, 1991	December, 1991.
F: Conservation and renewable energy reserve.	December, 1991.	May, 1992.
G: Small diesel refineries.	March, 1992	December, 1992.

On May 23, 1991, EPA published a notice of proposed rulemaking (NPRM) in the Federal Register (56 FR 23744) proposing regulations for conducting the auction and sale of allowances, as well as regulations governing the IPP written guarantee. The comment period for this notice expired on July 5, 1991. The comments received in response to this notice, as well as the procedures and conditions that are being adopted in this final rule, are discussed below. Editorial comments will not be discussed, but editorial changes have been incorporated where EPA believes appropriate.

II. Discussion of Comments

Thirty-four commenters with one hundred and twenty-nine comments responded to the May 23, 1991 notice. Commenters included twelve utilities, eight utility or energy-related trade associations, four public utility commissions, two environmental groups, one state environmental agency, one unaffiliated individual, one potential broker for allowances, and one commodity futures trading exchange.

Section 73.3 Definitions

In the rule, EPA has deleted the definition of "qualified applicant" because it was superfluous. EPA has added definitions for "owner" and "owner or operator" for the convenience of the reader. These definitions are proposed in the Allowance System Rule (40 CFR part 73, § 73.3) and commenters will have the opportunity to comment on them and on all other definitions that appear both here and in that rulemaking during the comment period for that rulemaking. Such definitions will become final when the Allowance System Rule is promulgated; should there be any changes in those definitions as a result of the comment period, the definitions printed here will be changed accordingly.

Section 73.7 Auctions

The Private Auction

The Act allows any person holding allowances to sell those allowances in auctions held by EPA [section 416(d)(4)], but requires that allowances from the auction subaccount must be sold before other offerings may be sold. Unlike EPA, other allowance holders may specify a minimum price for the allowances they offer. Subject to these two statutory provisions, EPA proposed to treat allowances offered from others as part of the total annual supply of allowances for sale in each auction held by EPA, including requiring that only allowances allocated for the year of the auction (or allowances banked from previous years' allocations) and seven-year-advance allowances may be offered.

EPA proposed that all bids to the auctions be ranked from highest to lowest on the basis of bid price. EPA would allocate and sell all the allowances in the auction subaccount on the basis of this ranking; when all such allowances were sold, EPA would match contributed allowances offered for sale with any remaining bids, as described in the next section.

Eleven commenters believe that EPA has interpreted incorrectly section 416(d)(4) of the Act, which governs the sale of contributed allowances, by proposing to sell the allowances offered from others, immediately following the sale of EPA allowances in a combined

auction. They argue that while this section does not specify that such private allowances should be sold in a separate auction, it does state that allowances shall be sold after the EPA auction is complete. Their preferred interpretation of this section would require EPA to hold a separate private auction so that sellers could offer a variety of allowance packages, including, for example, multi-year "streams" of allowances (*i.e.*, X allowances/year for Y years), rather than being limited to offering spot and seven-year-advance allowances. In addition, these commenters believe that separating the private part of the auction would allow participants time to evaluate bids and offers based on the results of the EPA auction.

Some of these same commenters have expressed concern that the facilitating mechanisms of the private market might be slow to develop in the early years of the regulatory program. This prospect would justify a separate, EPA-sponsored auction to "jump-start" the market, by facilitating contact between buyers and sellers who might not have other, more efficient means for making contact, and to provide the public with information concerning both offers and the market's response to such offers. In fact, some of these commenters argued that those brokers who will be active in the near term will offer only a proprietary and costly brokering function, mediating transactions based on limited, closely-held information, rather than providing their clients and the market with a broad vision of the entire market. Some public utility commissions (PUCs) expressed concern that they will not be able to evaluate utilities' decisions concerning allowances because of the lack of widely available price information.

Response: The rule remains unchanged from the proposal concerning the separation of private allowances from the EPA auction and the role of EPA in facilitating information exchange. EPA believes that incorporation of allowances offered from others as part of the total annual supply of allowances complies with the language in section 416(d)(4) of the Act. The language in the Act is broad and places few requirements on the conduct of the auction, all of which are met in the EPA proposal.

In the NPRM, EPA anticipated the comments expressed above and requested comment on an EPA-sponsored catalogue auction, catalogue exchange, and bulletin board. The catalogue auction was proposed to serve as the private auction where a variety of allowance packages could be offered and EPA would determine winners based on the highest bid price. The catalogue exchange and bulletin board are non-regulatory instruments designed to facilitate the exchange of information among potential market participants and other interested parties such as PUCs which EPA is free to institute at any time without engaging in a formal rulemaking. Though the Agency received some comments in favor of those options, EPA has decided not to adopt a catalogue auction in the final rule or implement at this time a catalogue exchange or bulletin board.

EPA's rejection of the catalogue exchange rests on EPA's clear commitment to promoting, or at least not impeding or competing with, private market solutions. To the extent that an allowance bulletin board or catalogue exchange would be valuable, EPA believes the market itself can be expected to provide such mechanisms. In fact, on July 17, 1991 the Chicago Board of Trade (CBOT) publicly announced its intention to create a futures market for allowances. The announcement is a strong, early indication that a sophisticated, self-sustaining private market for allowances is developing. As expressed in its comments to EPA, the CBOT also intends to offer market participants an electronic bulletin board system that will distribute information on allowances offered.

The CBOT's announced intention to create an allowance exchange is clear evidence that private enterprise will respond to real or anticipated needs. EPA also believes that other devices will enable the market to avoid the higher transaction costs associated with using brokers and their reliance on proprietary, closely-held information. Specifically, utilities and others seeking to buy or to sell can publish requests for proposal offering purchases or sales and inviting counter-offers. This approach would result in wider dissemination of information, while leaving the parties free to negotiate the terms of a proposed transaction.

EPA rejected sponsoring a separate catalogue auction because a strict auction format, in contrast to a party's ability to publish offers to sell or buy and to entertain counter-offers allowing for negotiation between parties, would be unsuitable for all but a negligible number of transactions. To satisfy the requirements of an auction format, sellers would be required to offer their allowance packages at a single price, and bidders would be compelled to accept an offer without a single variance or amendment. Given the complexity and variety of potential allowance packages and the number of variable terms (*e.g.*, timing of payment and delivery) from both buyers' and sellers' perspectives, EPA believes that most transactions could only be the result of direct negotiations between buyers and sellers. In addition to mechanisms that publish offers to buy and sell, the private market has brokerages and consulting firms to facilitate the matching of, and negotiations between, buyers and sellers.

Four commenters supported EPA's position of limiting its role in the development of information exchange mechanisms. PSI Energy stated in its comments:

> * * * That a private market for emission allowances will evolve without EPA needing to play a major role in its establishment. The utility industry has already seen several offers to sell allowances, as well as solicitation to purchase allowances. As the compliance deadline grows nearer and the first few transactions are finished, a robust market should develop.

In fact, three of these commenters believe that administration of an allowance market by the EPA would discourage the natural emergence of private trading mechanisms and could possibly be detrimental to the development of the allowance market.

These commenters believe, and EPA agrees, that since the Agency has no experience in constructing trading systems and monitoring markets to protect against fraud, market participants might be hesitant to participate in an EPA-sponsored catalogue auction or exchange. The allowance market is best served, they argue, if trading and information mechanisms are administered by experienced and proven private entities. These entities would not only facilitate individual transactions, but promote price and information discovery, which would lead, in turn, to increased market liquidity.

Finally, some analysts suggest that uncertainties concerning compliance costs, PUC action and future growth of electricity demand are likely to be the primary inhibitors of allowance trading. Uncertainties stemming from inadequate dissemination of information are less likely to pose a threat simply because, given the wide-spread belief that allowance trading can reduce costs, the market is very likely to solve problems involving the sharing of information quickly, efficiently and effectively. In view of that possibility, both the bulletin board and catalogue exchange, as well as the catalogue auction, could prove to

be superfluous at best, if not damaging to the development of mechanisms that the private market has fostered and will continue to foster.

The Matching of Private Allowances With Bids

With regard to the auction of SO_2 allowances, EPA proposed a matching scheme in which allowances with the lowest minimum prices (reservation price) offered by private parties would be matched with the highest bids that remained after the allowances in the Auction Subaccount were sold. Under this approach, privately offered allowances would be matched, in ascending order of minimum price, with remaining bids until either all bids are awarded, all privately contributed allowances are sold, or privately contributed allowances can no longer be matched with bids because the minimum price is higher than remaining bids.

Most commenters did not address this issue. However, some commenters suggested that an alternative matching scheme, one in which privately contributed allowances would be matched in descending order with the bids that remained after the auction of EPA allowances was completed (*i.e.*, offers of allowances with the highest minimum prices would be matched to the highest bids first) would be preferable. They argued that: (1) The proposed matching scheme is confusing and may result in no matches being made; (2) the alternative matching scheme could result in more allowances being sold in the auction; and (3) the proposed matching scheme encourages private offerors to specify minimum prices that are lower than they truly are willing to accept so as to be matched to the highest bids in order to increase the revenue generated from the sale. One commenter was concerned that this activity might result in artificially low price signals being sent to the market.

Response: As discussed above, EPA believes that in the trading of allowances, it is more likely that private mechanisms will be relied upon to sell allowances rather than the EPA auctions, regardless of the matching scheme employed in such auctions.

EPA proposed the low-offer-to-high-bid matching scheme, in part, to simplify the design of the "private" auction and to minimize EPA's burden in administering the auction. The proposed matching scheme is straightforward—the "offer curve" for private allowances takes the shape of a supply curve used in standard economic analysis and this allows offers to be matched unambiguously with bids. Further, the only time matches would fail under the proposed matching scheme is when the minimum prices specified by all offerors are higher than the highest bid remaining after the allowances in the Auction Subaccount are sold. In this situation no matching schemes, including high-offer-to-high-bid, would result in matches between offers and bids because minimum prices would still be higher than the remaining bids.

EPA believes that the high-offer-to-high-bid matching system that some commenters have suggested as an alternative would prove to be more complicated and could create difficulties in matching offers with bids. Under such a system, EPA would order the offers from high minimum price to low minimum price. Any offers with minimum prices higher than the highest bid remaining after allowances in the Auction Subaccount are sold would be discarded, and the remaining offers would be matched, in descending order, with the remaining bids. The problem with this approach is that separate segments of the resulting "descending offer curve" could be both above and below the bid curve depending on the bids and offers submitted in the auction. For example, if the bid prices for allowances decline more rapidly than the minimum prices specified in offers, a segment of the offer curve will be above the bid curve and no matches would be feasible; if the minimum prices declined by more than bid prices, the "offer curve" would cross over the bid curve and lie below it and matches would occur. It is not clear, however, how offers and bids should be matched in situations where bid and offer curves exhibited this "overlapping" behavior.

Table 3 below illustrates the concerns of adopting a high-offer-to-high-bid matching scheme:

TABLE 3.—HYPOTHETICAL EXAMPLE FOR MATCHING OPTIONS

Bids	Low to high ordering		High to low ordering	
	Minimum price	Bid successful?	Minimum price	Bid successful?
500	150	Yes	500	Yes.
500	175	Yes	500	Yes.
450	200	Yes	475	No.
400	200	Yes	450	No.
350	200	Yes	300	Yes.
300	300	Yes	200	Yes.
250	450	No	200	Yes.
200	475	No	200	Yes.
150	500	No	175	No.
100	500	No	150	No.

Table 3 assumes each bid and private offer are for an equal number of allowances. Under the low-offer-to-high-bid matching scheme, the sample auction clears 6 of the 10 bids, with a clearing price of $300, with the 4 offers with the highest minimum prices rejected. Under the high-offer-to-high-bid matching scheme, the sample auction clears 6 of the 10 bids. The lowest clearing price is $200, but two bids at much higher prices, $400 and $450, are rejected because the offers matched against them had set higher minimum prices. Such a result seems arbitrary and imposes considerable uncertainty on the bidders at the auctions. Such outcomes would in fact, make the high-offer-to-high-bid matching scheme a random selection process for filling bids, rather than a rational system that assured allowances to high bidders.

If a high-offer-to-high-bid matching scheme was adopted, the Administrator would have to develop a method for matching bids and offers that might require making partial matches or, alternatively, shifting the "offer curve" so that the offers with the lowest minimum prices could be matched with bids. Either approach would make administering the auction more difficult.

With regard to the second point made by commenters, standard supply-demand analysis suggests that the alternative high-offer-to-high-bid matching mechanism could result, in some situations, in more allowances being sold in the auction, but with a lower auction clearing price. This would create an anomaly, however, since this same analysis also suggests that those offerors able to sell their allowances at the auction would subsequently have an incentive to purchase allowances in the market that are available at the lower auction-clearing price (*i.e.* the lowest price at which allowances are sold at the auction). That is, sellers offering allowances at higher prices (presumably representing their marginal cost of reducing sulfur dioxide emissions) and selling them to the higher price bidders would then have an incentive to purchase other allowances at the lower auction-clearing price (which would presumably be lower than the sellers' marginal reduction costs). Such re-purchasing would negate the higher sales volume promoted by the commenter as a virtue of high offer to high bid matching.

The third point made by commenters is that the incentives created by the low-offer-to-high-bid matching system will lead to a systematic reduction in the expressed minimum prices that in fact will understate the offeror's true reduction costs. EPA believes this type of bidding behavior is unlikely in an

allowance market with even minimum activity. If an active allowance market is established apart from the EPA auctions, as EPA believes will occur, offerors are more likely to profit from sale of their allowances in a private transaction, in any event, than they could in a sale made in the EPA auctions. For this reason, EPA anticipates that more activity will occur in the market than in the auction of private allowances. In addition, a strategy of offering allowances at auction at a minimum price that understates actual reduction costs would make sense only if the offeror were assured that the auction would yield a better price for the allowances than would the private market. Such an outcome would not be likely: since offered allowances are sold after all EPA allowances have been sold, private offerors necessarily will receive a price that is lower than the clearing price in the auction of EPA allowances. Such a strategy could pose risks for the offeror, especially if the demand for allowances is uncertain, since the offeror must commit to the private auction before the bidding begins. If demand fluctuates, the offeror could end up selling allowances at a lower price than could be found in the market. Thus, EPA does not believe that a systematic reduction in requested minimum prices will occur. EPA will monitor each of the auctions, however, and identify any necessary changes to the design of the auction that may be required to assure an orderly and competitive market.

In sum, EPA believes that there are persuasive practical reasons for preferring the proposed low-offer-to-high-bid matching scheme. The proposed matching scheme offers more rational matching patterns and avoids the administrative difficulties that are likely to arise under the alternative matching scheme in the situation when bid and offer curves overlap. In addition, sales of allowances made under the proposed matching scheme might more approximate the genuine economic incentives of the allowance market. Some sales under the alternative matching scheme, in contrast, might not.

Withdrawal of Bids During the EPA Auction

One commenter questioned EPA's failure to propose to afford private offerors of allowances the option of withdrawing their offers from the EPA auction if fewer than the full number of allowances offered would be sold. EPA proposed to allow bidders to withdraw their bid if the full number requested cannot be supplied. EPA agrees that private offerors should be allowed to withdraw their offers if fewer than the full number of allowances offered would be sold. Accordingly, the final rule incorporates this suggestion.

The Contract or Delegation of the Auction Function

Section 416(f) of the Act authorizes the Administrator to provide, by delegation or contract, for the conduct of sales and auctions by other departments or agencies of the United States Government or by nongovernmental agencies, groups, or organizations.

One commenter suggested that EPA should contract out the auction function if EPA committed to offering a catalogue auction as addressed in the private auction discussion. The commenter proposed that the contractor charge a fee for administering the auction to offset the added expense of running a catalogue auction. At the same time, a second commenter expressed concern that EPA would contract out the auction function to an entity that would charge large fees for administering the auction. This commenter also suggested that the contract or delegation should be formally proposed through public rulemaking.

Response: As stated in the NPRM and reiterated herein, EPA has not yet made a determination as to the managing agent, if any, for the conduct of the auctions and direct sale. If the auctions and direct sale are administered by another entity on EPA's behalf, that entity would be unable to charge fees to cover its expenses. Finally, the Act does not require the Administrator to contract or delegate the administration of the auction through public rulemaking.

Section 73.71 Bidding

Publishing Losing Bidders Names

The Administrator is required by section 416(d)(5) of the Act to "publicly report the nature, prices, and results of each auction * * * including the prices of successful bids * * *. EPA proposed to publish the names of all bidders, their bids and the lowest price at which allowances are sold in each auction.

Three commenters were supportive of EPA's proposal to publish the names of all bidders and their bids. They believe full disclosure of this information is important to the functioning of the market and will assist state PUCs in their evaluation of utilities' decisions concerning allowances. They suggest that bidders could use the names of agents, surrogates, or brokers submitting bids on their behalf if they wished to avoid disclosure.

Ten commenters thought that EPA should not disclose losing bidders' names because this public information may put the losing bidder at a competitive disadvantage in negotiating to buy or sell allowances in a private transaction. These commenters also argued that the public disclosure of losing bidders' names is not useful to the allowance market.

Response: EPA agrees that publishing losing bidders' names could compromise the interests of these bidders in private negotiations and that the publication of this information is not important to the operation of the market. Therefore, EPA has decided not to publish losing bidders' names after each auction. This change is reflected in the final rule. EPA will be required, however, to respond to requests for this information under the Freedom of Information Act (FOIA) if such requests are received by EPA.

In the NPRM, EPA requested comment on a two-envelope bid process which would separate names from bids. This bidding process was proposed to avoid subjecting the identity of losing bidders to Freedom of Information Act (FOIA) requests, which EPA would be compelled to fulfill even if EPA received information identifying losing bidders simply in carrying out the mechanics of the auction. EPA received comments in favor of the two-envelope bidding process because losing bidders' names would not be published. EPA has concluded, however, that this process would pose substantial difficulties for both bidders and the Agency. As was pointed out by some commenters, it would be very difficult for EPA to segregate fully the identity of bidders from the information minimally necessary to process each bid. Each bidder necessarily would be identified in connection with the payment instruments required to be submitted with the bid or through the information supplied for purposes of return of payment. Even if a method for avoiding such an exchange of information could be devised, EPA believes the burden both bidders and EPA would incur to implement the two-envelope bid process would impair substantially the efficiency and speed with which each auction could be conducted. EPA does not believe such a burden is justified when other suitable options, such as that of using a surrogate's name, are available if bidders wish to avoid disclosure of their identities.

Method of Payment

EPA proposed that each auction bid must be accompanied by a certified check or a letter of credit (LOC) for the

total bid price or by some method of electronic transfer or other instrument, which EPA, following public notice, may require or permit at some future time.

Six commenters suggested that EPA presently allow electronic transfer as a method of payment for allowances after they had been awarded at the auctions since, compared to an LOC or a certified check, electronic transfer methods lower costs and processing time.

Response: The rule remains unchanged from the proposal. Electronic payment, as envisioned by the commenters, could not guarantee future payment and would only be executed after the allowance awards were made. No matter how quickly payment could be executed through electronic transfer, such a method would not fully preclude defaults by winning bidders if payment were not required with the submission of each bid.

EPA is requiring payment guaranteed either with a certified check or an LOC prior to the award of allowances to ensure integrity of each auction. Such an approach is implied by the express elements of section 416 of the Act. The Act makes no provision for the awarding of allowances to a successful bidder by any method other than certain, direct, and immediate payment. If EPA did not require guaranteed payment with bids, winning bidders could default on their payments, requiring EPA to recalculate allowance awards. Such a process could delay the resolution of pending bids and undermine the stability of the auction process. However, EPA, following public notice, may require or permit at some future time a method or methods of electronic transfer or other instrument for payment of allowances awarded at the auctions if such methods can ensure guaranteed payment prior to the calculation of the allowance awards.

EPA proposed that to qualify as an LOC, such instrument must ensure that EPA will receive full payment for allowances awarded at the auction no later than 24 hours after the results of the auctions are announced in the Allowance Tracking System. Two commenters stated that 24 hours may not be enough time to process the funds transfer; it may also be impossible if the results of the auction are announced on a Friday. They suggest that 2 business days following the announcement of the results of the auctions in the Allowance Tracking System is a more reasonable time period to ensure EPA will receive full payment for allowances. EPA agrees with these comments and has incorporated this suggestion in the final rule accordingly.

Unrestricted Bidding

EPA proposed no restrictions on who may bid in the auctions or the number of allowances that may be sought in any one bid. One commenter suggested that EPA restrict bidding to only affected units needing allowances for compliance purposes. The commenter argues that an auction with unlimited participation could create artificially high prices for allowances. The commenter also suggested that EPA restrict the number of allowances a bidder may seek to a number no greater than 120% of the utility's average sulfur dioxide emissions for the preceding five years. Such a restriction, the commenter argued, would prevent hoarding of allowances or price-fixing by a group of utilities.

Response: The final rule remains unchanged from the proposal. Section 416 of the Act imposes no restrictions on who may bid in the auction and gives EPA no express authority to do so. EPA, however, is well aware of the recent controversy surrounding the auction of government securities conducted by the Federal Reserve on behalf of the Department of Treasury. The most important problems that have surfaced regarding these auctions are that:

(1) Major bidders may have shared information and may have colluded in setting bids in some auctions; and

(2) Limitations on the share of a given bond issue that any one bidder can obtain at auction were violated on several occasions. In view of this situation, EPA believes it is important to highlight the differences between the Treasury auction and the EPA auctions and explain how the problems occurring in the Treasury auction are unlikely in the EPA auctions.

Critics of Treasury auctions recently have argued that the auction design as discriminating, rather than as uniform, increases the incentives for bidders to collude. Although EPA's allowance auction is also a discriminating price auction, EPA believes a number of factors distinguish it from the Treasury auctions and reduce the likelihood of collusion among bidders.

In the Treasury auction, a limited number of primary bidders have an advantage in placing bids and in consulting with Treasury in regards to its financial strategy. In the EPA auctions, in contrast, any party may participate. Participation is not limited to a specific class of bidders (e.g., utilities), nor are any special privileges accorded to any class of bidders. Thus, a potentially large number of geographically dispersed bidders are likely to participate in the EPA auctions and the group of bidders is likely to vary from year to year. Additionally, the EPA auctions will be run once per year, rather than many times per year as is characteristic of Treasury auctions, which will tend to make the EPA auctions involve a greater number of bidders. This will tend to limit the ability of participants to familiarize themselves with competing bidders and should raise the cost of coordinating bidding strategies, as compared to that in auctions held more frequently and involving a census of bidders that is smaller and more well defined. Hence, free entry to the EPA auctions should make collusion to influence the auction clearing price a difficult and ineffective strategy.

Second, EPA will computerize all bids and will make public the names of, and prices paid by, winning bidders. This procedure will further reduce the incentive for bidders to collude because such bidding practices would be readily detectable.

Unlike the Treasury auction, EPA's auctions will have no limits on the share of allowances that any one bidder may obtain in the auction. At this time, EPA does not believe there are any compelling reasons to restrict the number of allowances for which a single bidder may bid, or restrict the submission of multiple bids. In particular, attempts at hoarding or price-fixing allowances would be subject to anti-trust laws and, to the extent utilities are involved with such practices, subject to review by public utility commissions. Restrictions on bidding without good cause may inhibit the efficiency of the EPA auctions and signal unsubstantiated distrust of the new allowance market.

Although EPA excepts the allowance auction, as designed, to function properly, EPA will monitor each of the auctions and identify any necessary changes to the design of the auction that may be required to assure an orderly and competitive market.

Timing of the Annual Auction

EPA proposed to hold the spot auction and the advance auction on the same day, no later than March 31, in each calendar year beginning in 1993. One commenter suggested that EPA hold the auction some time during the period between December 31 and the allowance transfer deadline which is the last day allowance transfers may be submitted to EPA for recordation in affected units' accounts for use in meeting their emissions limitations requirements for the preceding year. This would enable allowances sold in

the auction to be used for end-of-year compliance needs. Another commenter suggested that EPA hold the auctions in late summer for the same purpose.

Four commenters supported the EPA proposal.

Response: The final rule remains unchanged from the proposal. Holding the auctions prior to March 31 will allow those needing to acquire allowances, such as the operators of new IPP units, the opportunity to do so at an auction price before having to resort to buying allowances for $1,500 in the direct sale, which will immediately follow the auctions. Holding auctions early in the year will also allow new and existing units time to plan for end-of-the-year compliance. If utilities need to buy spot allowances for end-of-the-year compliance, the direct sale will serve that purpose for those unable to purchase allowances in the private market.

Disposition of Unsold Allowances

Section 416(c)(6) of the Act mandates that any unsold allowances from the direct sale must be transferred from the direct sale into the Auction Subaccount. EPA proposed that the unsold spot allowances will be sold in the following year's spot auction and that any unsold advance sale allowances be transferred into the Auction Subaccount and be sold as spot allowances when the allowances became useable for offsetting SO_2 emissions, according to their compliance use dates. EPA proposed this approach because advance allowances transferred from the advance sale into the Auction Subaccount would, at the time of their transfer, have a compliance use date of six years in the future, which would be inconsistent with the seven-year advance auction mandated by the Act.

Eight commenters objected, however, to the holding of advance sale allowances for seven years until they could be sold as spot allowances. They argued that holding allowances deprives utilities of their statutory compensation either in the form of payment from sale of their allowances or return of their allowances if they remain unsold in the annual auction. EPA's proposal, they argued, would also be inconsistent with the policy, established elsewhere in the proposal, of distributing both the proceeds of the sale and unsold allowances promptly.

Response: EPA agrees with the commenters' objections. Because the Act simply mandates the transfer of unsold allowances to the Auction Subaccount, EPA does not believe the Act bars the sale, at auction, of advance allowances on a six-year basis if such allowances are first offered for sale, but are not sold, as seven-year advance allowances.

The final rule reflects EPA's intention to offer in the advance auction, as six-year advance allowances, any allowances initially offered as seven-year allowances in the direct sale but not sold, as well as seven-year advance allowances. Bidders in the advance auction will simply indicate on their bid form which allowances (six- or seven-year advance) they are seeking. Bids for these allowances will be ranked from highest to lowest and awarded accordingly. The method of processing and awarding bids for these allowances, and the distribution of the proceeds from the auction, will be the same as those for seven-year advance and spot allowances. EPA believes that this approach responds to the commenters' objections since it eliminates the retention of unsold allowances in the Auction Subaccount for six years.

Section 73.72 Direct Sales

In anticipation of the possibility that the Direct Sales Subaccount may be oversubscribed by the total number of applications submitted in any one year, EPA proposed to create a "waiting list," on a first come, first served basis. EPA proposed that "wait-listed" applicants only be approved if previously reserved allowances become available and if ample time (at minimum, five business days) for payment and transfer remains in the direct sale period.

As authorized under section 416(c)(2) of the Act, applicants may reserve allowances for direct sale without paying a deposit until six months after approval of their application; therefore, applicants could reserve allowances less than six months prior to the end of the direct sale and cancel their reservation at the very end of the sale without penalty. Wait-listed applicants could fail to acquire allowances simply as a result of the proposed time constraints, even though allowances would in fact remain unpurchased by those whose applications had initially been approved. For this reason, eight commenters argued that EPA's proposal reduced the value of the waiting list while doing nothing to discourage potential buyers from reserving more allowances than they needed. Commenters suggested that full payment for reserved allowances be required thirty days prior to the end of the direct sale "wait-listed" applicants an opportunity to purchase allowances from the direct sale.

Response: EPA agrees with the commenters' position. As reflected in the final rule, the Administrator will assess the allowance reservation status of the direct sale subaccount on December 1 of each year the direct sale is held. In the event that the direct sale is oversubscribed by December 1, the Administrator will require full payment for reserved allowances no later than 30 calendar days prior to the allowance transfer deadline ("the oversubscription payment deadline") for those applicants whose applications were previously approved and for whom allowances were reserved. The Administrator will transfer allowances to applicants at the time full payment is received. The reservation of direct sales allowances and the waiting list process remain the same as proposed. After the oversubscription payment deadline has passed, the Administrator will reserve allowances, if any, for the wait-listed applicants according to the applicants' rank on the waiting list. The Administrator will notify such applicants of their rank and the amount of allowances reserved for them. If applicants without reserved allowances wish to contact those wait-listed applicants for whom allowances have been reserved, in case such applicants choose not to purchase their reserved allowances, EPA will make such information available upon request. Full payment for allowances must be received by EPA on or before the allowance transfer deadline.

If the direct sale is not oversubscribed by December 1, the Administrator will continue to reserve allowances remaining in the direct sale subaccount in the order of receipt of the applications, up to 10 calendar days prior to the allowance transfer deadline. Ten business days are necessary for EPA to notify approved applicants and receive payment prior to the end of the direct sale. Full payment must be received by EPA on or before the allowance transfer deadline.

Distribution of Proceeds From the Direct Sale and the Annual Auctions

The Act mandates that the Administrator distribute all proceeds from the direct sale (including deposits by approved applicants who fail to complete purchases) within 90 days after the direct sale ends, and proceeds from the annual auction within 90 days after the auction ends. Proceeds are distributed on a pro rata basis to units that had allowances withheld from their initial allocation of allowances for purposes of the direct sale and annual auctions. EPA proposed to carry out these redistributions by the statutory deadline although the Agency, as expressed in the NPRM, intends to

distribute proceeds more quickly. EPA also proposed to transfer proceeds to the owners of contributed allowances shortly after the auction.

A few commenters requested that EPA specify a regulator deadline for returning proceeds from the sale and auctions that is shorter than the 90 days allowed by section 416 of the Act. One commenter suggested a deadline of 10 business days to return proceeds after the sale and auction.

Response: The final rule remains unchanged from the proposal. Although EPA is unwilling to impose a shorter regulatory deadline, it intends to return the proceeds as expeditiously as possible, well before the maximum 90 days permitted under the Act. Establishing a shorter period by regulation would not accelerate the rapid distribution of proceeds, which the Agency already intends, nor would it afford those entitled to the proceeds any additional practicable remedy or recourse.

Section 73.73 Independent Power Producers Written Guarantee

Termination of the Written Guarantee

EPA proposed that IPPs issued written guarantees demonstrate to EPA the following, to continue to hold their guarantees:

1. Continued good faith efforts to obtain allowances. Section 416(c)(4)(b) states that the Administrator may terminate a written guarantee if continued efforts to obtain allowances are not pursued.

2. Timely commencement of commercial operations. EPA proposed to terminate a written guarantee if the unit for which a guarantee is issued has not commenced commercial operation by the later of January 1, 2000 or within two years of the date stated in the guarantee.

3. Notification of continued need for the guarantee. Lastly, EPA proposed to terminate a written guarantee if the responsible official for the IPP fails to notify EPA semi-annually until 1993 and annually thereafter of the continued need for the guarantee. The notification would include information on any allowances acquired through other means; EPA would deduct the number of allowances from the number initially guaranteed. EPA proposed in effect, to terminate guarantees, at least in part, to the extent, and only to the extent, the acquisition of allowances met part, or all, of the unit's allowance needs.

Comments and responses: One commenter requested that EPA allow IPPs to petition EPA for a deferral of termination of the guarantee if the projected start-up date of the unit is delayed beyond the two years allowed after the date stated in the guarantee. EPA has concluded, however, that such a concern is merely speculative and that the two-year delay is sufficient to accommodate whatever setbacks may be faced by units nevertheless destined to begin operation. Accordingly, the final rule remains unchanged from the proposal on this issue.

One commenter stated that EPA should add the failure of an IPP project as a condition for termination of the guarantee. EPA believes that project failure would be revealed in the certification of the continued need for the guarantee, prompting EPA to terminate the guarantee.

The commenter also argued that IPP certification of the continuing need of the guarantee was an excessive requirement and that EPA could simply require IPPs to notify EPA when their project had failed or when they obtained some or all of the needed allowances. EPA believes that the certification requirements is important in the likely event that there is an oversubscription to the guarantee program. EPA, seeking to safeguard the interests of IPPs waiting to obtain guarantees following initial oversubscription of the program, cannot rely on IPPs with guarantees to notify EPA as soon as their status has changed, since the IPPs may have little incentive to do so. The certification of continued need as a prerequisite for continuing the guarantee assures IPPs' diligence in notifying EPA of any changes in their status.

One commenter apparently misunderstood the NPRM, believing that EPA proposed to terminate a guarantee if allowances were obtained in a number only partially fulfilling the unit's needs. EPA believes the language in the rule to be clear, but that the wording in the preamble was misconstrued. As proposed and as reflected in the final rule, EPA will reduce only the number of allowances guaranteed for that year or years by the number of allowances obtained from other sources.

Issuing Guarantees to Units

EPA proposed that guarantees be issued for a unit and not to the unit's owners and may only be transferred with the unit itself. One commenter suggested that EPA issue guarantees to developers of IPP projects since such projects are typically owned by developers initially. The commenter also stated that guarantees should be able to be applied to any other project that the developer may own or initiate.

The commenter also asked whether operational changes made to, or planned for, a unit subsequent to the issuance of a guarantee would affect the guarantee.

Response: Under the Act, allowances are required for affected units to offset their sulfur dioxide emissions. In addition, the Act makes clear that a unit's eligibility for a guarantee and the number of allowances subject to the guarantee are to be determined on the basis of required showings concerning facts specific to the unit. Since each guarantee application pertains to one specific unit, there would thus be no justification for transferring guarantees to other units or entities.

The commenter's second question concerned operational changes made to a unit subsequent to the issuance of a guarantee, and the possibility that such changes could result in the guarantee failing to ensure that the unit's future allowance needs will be met. An IPP needing additional allowances because of unforeseen circumstances must obtain the additional allowances in the private market, in the EPA auction or direct sale, or reapply to the guarantee program for the new number of allowances needed. EPA will not add allowances to the number guaranteed for a unit for changed operations after issuance of the guarantee. Usually such changes require new financing. If EPA issued additional allowances without new information, EPA and IPP financiers could not ensure that the showings presented for the previous unit corresponded to the characteristics and circumstances of the changed unit. In addition, adjustments to guarantees already issued would jeopardize the certainty in the reservation of allowances and the integrity of the guarantee program.

"Useful life" of the Unit

EPA proposed that duration of the guarantee is up to 30 years (the useful life of the unit), beginning in the year 2000. One commenter thought that EPA should conduct a separate rulemaking on what constitutes the "useful life" of the unit and not simply declare it to be 30 years.

Response: EPA has chosen 30 years as the operating life of the unit in order to be consistent with the time period commonly chosen by financial institutions for the purposes of financing IPP projects. Since the guarantee is a means for IPPs to demonstrate to their financial lenders that they have access to a sufficient number of allowances to operate planned facilities fully, the guarantee must continue for the duration of the financing. EPA intends that the definition of "useful life" of the unit apply only for purposes of determining

the duration of the written guarantee. The final rule remains unchanged from the proposal.

Application for a Written Guarantee

EPA proposed that written guarantees be processed and approved according to the order in which applications are received, beginning with the date the regulations go into effect. EPA will time- and date-stamp applications as they are received.

As mandated by section 416(c)(3) of the Act, the Administrator must provide written guarantees to qualified applicants within 30 days of receiving the application. Applicants who have filed applications that are deficient will have their applications returned as soon as the deficiencies are discovered and those applicants will receive a new time- and date-stamp upon their resubmission. Revised applicants will be processed according to the date on which they are filed.

One commenter suggested that EPA allow IPP applications with minor errors to be allowed to retain their original time- and date-stamp while the errors are being corrected instead of having to reapply and begin again with a new time- and date-stamp.

Response: As is stated in the rule, the Agency retains discretion in determining whether an error defeats the approval of an applicant or whether some action short of complete resubmission may suffice to correct the error. EPA believes it must be stringent with respect to deficient applications because EPA is mandated by the Act either to disapprove an application or to issue a guarantee within 30 days after receipt. EPA believes that its primary obligation is to IPPs that submit complete applications and that it should not delay the issuance of guarantees to those IPPs with approvable applications in effect for the benefit of an earlier applicant whose initial submission was not complete.

"Responsible Official"

EPA proposed that certification of all requirements in the application for a written guarantee shall be made by a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation. For a partnership a general partner would make the certification. The responsible official will be the contact person for all correspondence between EPA and the IPP concerning the written guarantee. Changes to the name of the responsible official must be made in writing to EPA.

One commenter asked why EPA did not allow or require the designated representative to be the responsible official.

Response: The final rule remains unchanged from the proposal except that the term "responsible official" has been changed to "certifying official" in order to avoid confusion with the term "responsible official" used in regulations issued under title V under the Act. The definition, however, has been expanded slightly to be usable for all of part 73. The rule neither prohibits nor requires the naming of the designated representative as the certifying official. When IPPs apply for written guarantees in 1991–1993, they may not yet have submitted their designated representative certifications.

Payment For Guaranteed Allowances

EPA proposed that allowances purchased pursuant to guarantees must be purchased by certified check for the total amount. One commenter questioned why EPA did not allow electronic transfer or other instruments to be announced, following public notice, to pay for these allowances, as it proposed for the auction and direct sale.

Response: The final rule is changed from the proposal to allow for electronic transfer or other instruments to be announced following public notice, which EPA may require or permit at some future time for the payment of allowances purchased through an IPP written guarantee. EPA did not intend to exclude this option for the IPP written guarantee; it was an oversight.

Miscellaneous

One commenter mistakenly thought that the proposed regulations provided that IPPs would have to pay 50% of the allowances guaranteed within six months after they were issued the guarantee. Direct sale applicants are required by the Act to pay 50% of the total purchase price within six months after their request to purchase has been approved by EPA.

As was stated in the NPRM, EPA interprets the Act to require no payment or deposit upon the issuance of a guarantee. Section 416(c)(2) of the Act requires that each applicant shall be required to pay the first half of the total purchase price within 6 months after the approval of the request to purchase. EPA does not believe the word "applicant" in section 416(c)(2) refers to holders of written guarantees, who, by definition, have been granted the purchase rights under the program. Any other interpretation would defeat the apparent overall purpose of the guarantee program: to provide certain assurances to IPPs, before they secure financing, while affording them subsequent opportunities to obtain allowances in the market. In addition, IPPs with guarantees do not need the six months delay to pay the first half of the total purchase price in order to secure a better purchase price for allowances while holding a place in the direct sale, because the guarantee affords them the right of first refusal. Therefore, EPA simply requires IPPs to pay full price for their allowances when they choose to exercise their guarantee.

As part of the application for an IPP written guarantee, EPA proposed that an IPP demonstrate it has met any one of the following milestones:

(1) It has been selected as a winning bidder in a utility competitive bid solicitation;

(2) It has entered into a fully binding power sales agreement;

(3) It has entered into a fully binding fuel supply agreement;

(4) It has received a site lease or proof of land acquisition;

(5) It has entered into a fully binding steam sales agreement; or

(6) It has submitted a complete environmental permit(s) application or has received such a permit(s).

One commenter asked the question whether escape clauses in power sales agreements could be construed to mean not "fully binding."

EPA added the words "fully binding" to the requirements listed above to ensure that the power, fuel, or steam sales agreements do not contain major contingencies or conditions that could jeopardize the implementation of the agreement. EPA does not consider clauses in contracts that protect lenders' and utilities' interests prior to the operation of the plant to compromise binding agreements. These types of clauses are considered standard in legally binding contracts. Since the words "fully binding" could be construed to disallow standard exemption clauses in IPP project development contracts, EPA has changed the words in the power, fuel and steam sales agreements from "fully binding" to "legally binding."

III. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, the Administrator must judge whether a regulation is "major" and therefore subject to the requirement to conduct a regulatory impact analysis. This final rule is not major as defined in section 1(b) of E.O. 12291, because of the

following reasons: the annual effect of the rule on the economy will be less than $100 million; it will not cause any significant increase in costs or prices for any sector of the economy or for any geographic region; and it will not result in any significant adverse effects on competition, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. EPA's economic analysis estimates that the total impact for participants in the auctions, direct sales, and IPP written guarantee program are minimal. The estimated number of bidders for each auction will be between 200 and 400, and each bidder is estimated to submit one to three bids. The number of direct sale applicants is estimated at 100 over two years. The number of applicants for the IPP written guarantee program is estimated to total 100 and is assumed to occur in the first year, 1992.

The total estimated annual costs to each auction participant range from $14,100 to $84,600. The estimated total costs for each direct sale applicant is $14,100 over two years. Assuming all IPP guarantee applications occur in the first year, the total cost to IPP guarantee applicants is estimated to be $235,000. The Agency anticipates that these proposed regulations will not have a significant effect on competition, costs, or prices. Therefore, EPA has determined that these final regulations are not "major."

The analysis is contained in the Economic Analysis of the Proposed Acid Rain Regulations for Auctions, Direct Sales, and IPP Written Guarantees, March 1991, EPA, Office of Atmospheric and Indoor Air Programs.

This final rule was submitted to the Office of Management and Budget (OMB) for review prior to publication as required by E.O. 12291.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires each Federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a "significant impact on a substantial number of small entities."

EPA has three reasons for expecting that the auctions, direct sales, and IPP guarantee regulations will not have significant impacts on small entities. First, the costs to any one entity of participating in the auctions, direct sales, or IPP guarantees are too small to affect the financial health of a participating firm of any size. Second, because participation is voluntary, entities can choose not to incur any of the costs if they do not expect to gain from participation. Finally, the benefits of the programs are likely to flow disproportionately to small entities, as the intended target of assistance from the direct sales and IPP guarantee programs. The auction is designed to ensure that all entities have an essentially equal chance to secure allowances, with minimal transaction costs. Based on this analysis and pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this attached rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq* and have been assigned control number 2060–0221.

The public reporting burden for this collection of information is estimated to average 48.5 hours per IPP guarantee application including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing the collection of information, and securing means of payment.

The information collection requirements associated with the letter of credit form in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. EPA proposed that bidders submit a letter of credit. EPA has since determined that a standard form for the letter of credit will be less burdensome for bidders and will facilitate EPA review of bid applications. An Information Collection Request document has been prepared by EPA (ICR No. 1584.03) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 or by calling (202) 260–2740. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

Public reporting burden for this collection of information is estimated to vary from 1 to 9 hours per response with an average of 5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing these burdens, to Chief, Information Policy Branch, PM–223Y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 73

Acid rain, Air pollution control, Electric utilities, Sulfur dioxide, Reporting and record-keeping requirements.

Dated: December 4, 1991.

F. Henry Habicht, II,

Acting Administrator.

For the reasons set forth in the preamble, title 40, chapter I of the Code of Federal Regulations is amended by adding part 73 as follows:

PART 73—SULFUR DIOXIDE ALLOWANCE SYSTEM

Subpart A—Background and Summary

Sec.

73.1 Purpose. [Reserved]
73.2 Applicability. [Reserved]
73.3 Definitions.
73.4 Deadlines.

Subpart B—Allowance Allocations [Reserved]

73.11–73.29 [Reserved]

Subpart C—Allowance Tracking System [Reserved]

73.30–73.49 [Reserved]

Subpart D—Allowance Transfers [Reserved]

73.50–73.69 [Reserved]

Subpart E—Auctions, Direct Sales, and Independent Power Producers Written Guarantee

73.70 Auctions.
73.71 Bidding.
73.72 Direct sales.
73.73 Delegation of auctions and sales and termination of auctions and sales.
73.74 Independent power producers written guarantee.
73.75 Application for an IPP written guarantee.
73.76 Approval and exercise of IPP written guarantee.
73.77 Relationship of independent power producers written guarantee to the direct sale subaccount.

Subpart F—Conservation and Renewable Energy Reserve [Reserved]

73.80–73.89 [Reserved]

Authority: 42 U.S.C. 7651.

Subpart A—Background and Summary

§ 73.1 Purpose. [Reserved]

§ 73.2 Applicability. [Reserved]

§ 73.3 Definitions.

The terms used in this subpart shall have the meaning given in the Act, and in this section, as follows:

Additional advance auction means the auction of advance allowances that were offered the previous year for sale in an advance sale.

Administrator means the Administrator of the United States Environmental Protection Agency or the Administrator's duly authorized representative.

Advance allowance means an allowance that may be used for purposes of compliance with a unit's sulfur dioxide emissions limitation requirements beginning no earlier than seven years following the year in which the allowance is first offered for sale.

Advance Auction means an auction of an advance allowance.

Advance Sale means a sale of an advance allowance.

Affiliate is defined as in section 2(a)(11) of the Public Utility Holding Company Act of 1935, 15 U.S.C. 79b(a)(11).

Allowance means an authorization, allocated by the Administrator under the Acid Rain program, to emit up to one ton of sulfur dioxide during or after a specified calendar year.

Allowance Tracking System means the system by which the Administrator allocates, records, and tracks allowances.

Allowance Tracking System account means an account in the Allowance Tracking System established by the Administrator for purposes of allocating, holding, transferring, and using allowances.

Allowance transfer deadline means midnight of January 30 or, if January 30 is not a business day, midnight of the first business day thereafter, and is the last day on which allowances may be submitted for recordation in an affected unit's compliance subaccount for the purposes of meeting sulfur dioxide emissions limitation requirements for the previous calendar year.

Auction Subaccount means an account in the Special Allowance Reserve, as specified in section 416(b) of the Clean Air Act. The Auction Subaccount shall contain allowances to be sold at auction in the amount of 150,000 per year from 1995 through 1999, inclusive, and 200,000 per year for each year beginning in the calendar year 2000, subject to modifications noted in these regulations.

Authorized account representative means a natural person who may transfer and otherwise dispose of allowances held in an account in the Allowance Tracking System, including, in the case of a unit account, the designated representative of the owners and operators of an affected unit.

Certifying official, for purposes of part 73, means:

(1) for a corporation, a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation;

(2) for a partnership or sole proprietorship, a general partner or the proprietor, respectively; and

(3) for a local government entity or State, Federal or other public agency, either a principal executive officer or ranking elected official.

Commenced commercial operation means to have begun to generate electricity for sale, including test generation.

Compliance use date means the first calendar year for which an allowance may be used for purposes of meeting a unit's sulfur dioxide emissions limitation requirements.

Consumer Price Index (CPI) means the United States government's primary indicator of the monetary inflation rate as published monthly by the U.S. Department of Labor, Bureau of Labor Statistics, Consumer Price Indices Branch, in the CPI Detailed Report and in the Monthly Labor Review. For purposes of part 73, the Administrator will use the "Consumer Price Index for all urban consumers for the US City Average, for all Items on the Official Reference Base" (CPI–U), or if such index is no longer published, such other index as the Administrator in his discretion determines meets the requirements of the Clean Air Act Amendments of 1990.

(1) CPI (1990) means the most recently adjusted CPI for all urban consumers as of August 31, 1989. The CPI for 1990 is 124.6 (with 1982–1984 = 100).

(2) CPI (year) means the most recently adjusted CPI for all urban consumers as of August 31 of the previous year.

Direct Sale Subaccount means an account in the Special Allowance Reserve, as defined in section 416(b) of the Clean Air Act. The Direct Sale Subaccount will contain Phase II allowances to be sold in the amount of 25,000 per year, beginnning in calendar year 1993 and of 50,000 per year beginning in the calendar year 2000.

Fuel supply agreement means a legally binding document between a firm associated with a new independent power production facility (IPPF) or a new IPPF and a fuel supplier that establishes the terms and conditions under which the fuel supplier commits to provide fuel to be delivered to a specific new IPPE.

New independent power production facility means, for purposes of this part, a unit(s) that:

(1) Commences commercial operation on or after November 15, 1990;

(2) Is nonrecourse project-financed, as defined in 10 CFR part 715;

(3) Sells 80% of electricity generated at wholesale; and

(4) Does not sell electricity to any affiliate or, if it does, demonstrates it cannot obtain the required allowances from such an affiliate.

Owner means any of the following persons:

(1) Any holder of any portion of the legal or equitable title in an affected unit; or

(2) Any holder of a leasehold interest in an affected unit; or

(3) Any purchaser of power from an affected unit under a life-of-the-unit, firm power contractual arrangement as that term is used in section 408(i) of the Act. However, unless expressly provided for in a leasehold agreement, owner shall not include a passive lessor, or a person who has an equitable interest through such lessor, whose rental payments are not based, either directly or indirectly, upon the revenues or income from the affected unit.

Owner or operator means any person who is an owner or who operates, controls, or supervises in any way an affected unit or affected source of which an affected unit is a part, and shall include, but not be limited to any holding company, operating company, utility system, designated representative, or plant manager of an affected unit or affected source.

Oversubscription payment deadline means 30 calendar days prior to the allowance transfer deadline.

Power sales agreement is a legally-binding document between a firm associated with a new independent power production facility (IPPF) or a new IPPF and a regulated electric utility that establishes the terms and conditions for the sale of power from a specific new IPPF to the utility.

Site lease is a legally-binding document signed between a firm associated with a new independent power production facility (IPPF) or a new IPPF and a site owner that establishes the term and conditions under which the firm associated with the new IPPE has the binding right to

utilize a specific site for the purposes of operating or constructing the new IPPF.

Spot allowance means an allowance that may be used for purposes of compliance with a unit's sulfur dioxide emissions limitations requirements beginning in the year in which the allowance is offered for sale.

Spot Auction means an auction of a spot allowance.

Spot Sale means a sale of a spot allowance.

Steam sales agreement is a legally-binding document between a firm associated with a new independent power production facility (IPPF) or a new IPPF and an industrial or commercial establishment requiring steam that sets the terms and conditions under which a specific new IPPF will provide steam to the establishment.

Unit means a fossil fuel-fired combustion device.

Utility competitive bid solicitation is a public request from a regulated electric utility for offers to the utility for meeting future capacity needs. A new independent power production facility (IPPF) may be regarded as having been "selected" in such solicitation pursuant to section 405(g)(6)(A)(iv) if the utility has named the IPPF as a project with which it intends to negotiate a power sales agreement.

§ 73.4 Deadlines.

In any year in which the deadline for an action authorized or required under this Part falls on a non-business day, the deadline will be the first business day after the date stated in this part.

Subpart B—Allowance Allocations [Reserved]

§§ 73.11–73.29 [Reserved]

Subpart C—Allowance Tracking System [Reserved]

§§ 73.30 to 73.49 [Reserved]

Subpart D—Allowance Transfers [Reserved]

§§ 73.50 to 73.69 [Reserved]

Subpart E—Auctions, Direct Sales, and Independent Power Producers Written Guarantee

§ 73.70 Auctions.

(a) *Allowances to be auctioned.* Every year the Administrator will auction allowances from the Auction Subaccount, established pursuant to Subpart B of this Part, according to the following schedule:

TABLE 1.—ALLOWANCE SCHEDULE FOR AUCTIONS

Year of purchase	Spot auction	Advance auction
1993	[b] 50,000	[a] 100,000
1994	[b] 50,000	[a] 100,000
1995	50,000	[a] 100,000
1996	150,000	[a] 100,000
1997	150,000	[a] 100,000
1998	150,000	[a] 100,000
1999	150,000	[a] 100,000
2000 and after	100,000	[a] 100,000

[a] Not useable until 7 years after purchase.
[b] Not useable until 1995.

In addition to the allowances listed above, the Administrator will auction allowances pursuant to paragraph (c) of this section and § 73.72(q) in the amounts and at the times provided for therein.

(b) *Timing of the auctions.* The spot auction and the advance auction, and, if required pursuant to § 73.72(q), an additional advance auction will be held on the same day, selected each year by the Administrator, but no later than March 31 of each year. The Administrator will conduct one spot auction and one advance auction, and, if required to § 73.72(q), one additional advance auction in each calendar year.

(c) *Submittal for other allowances for auction.* Authorized account representatives may offer allowances for sale at auction, provided that allowances are dated for the year in which they are offered or for any previous year or for seven years following the year in which they are offered. Such authorized account representatives may specify a minimum price for the allowances offered at the auctions. The authorized account representative must notify the Administrator fifteen business days prior to the auctions, using the SO_2 Allowance Offer Form published by the Administrator, or by means of electronic communication if the Administrator, following public notice, so requires or permits at some future time. The notification shall include:

(1) The compliance use date of the allowances offered;

(2) The number of allowances to be sold and any other information identifying the allowances offered that may be required by Subpart C of this Part;

(3) Any minimum price in whole dollars; and

(4) Whether the authorized account representative is willing to sell fewer allowances than the number stated in paragraph (c)(2) of this section, if the full amount cannot be sold. After notification, the Administrator will deduct allowances from the appropriate Allowance Tracking System account from which allowances are being offered and place them in a separate subaccount for such allowances.

(d) *Conduct of the auctions.* (1) The Administrator will rank all bids in descending order of bid price starting with the highest. Allowances will be sold from the Auction Subaccount in this order at the amounts specified in the bids until there are no allowances in the subaccount. If all allowances are sold from the Auction Subaccount, including unsold allowances transferred from the preceding year's direct sale, and if bids still remain, the Administrator will sell allowances offered by the authorized account representatives, beginning with those offered at the lowest minimum price. Allowances offered at the lowest minimum price will be matched with the highest bid remaining after the Auction Subaccount is exhausted. Sales of offered allowances, including, but not limited to, allowances offered by more than one offeror at the same minimum bid price, will continue in ascending order of minimum price, starting with the lowest, and descending order of remaining bids, starting with the highest, until:

(i) All allowances are sold,

(ii) No bids remain, or

(iii) Prices of remaining bids do not meet minimum prices required in remaining offers.

(2) In the event that there is more than one bid submitting the same price and the total number of allowances requested in all such bids exceeds the number of allowances remaining, the Administrator will award the remaining allowances by lottery to such bidders.

(3) In the event that there are more offers of sale at the minimum price than there are bids meeting that price, allowances from all such offers will be sold to cover the bids, according to each such offeror's pro rata share of all allowances so offered.

(4) In the event that fewer allowances remain than are requested in a bid, the Administrator will sell such remaining allowances to the bidder provided that, pursuant to § 73.71(b)(4), the bid states the bidder's willingness to purchase fewer allowances than requested in the bid.

(5) In the event that fewer than all allowances included in an offer for sale would be sold to remaining bids based on price, the Administrator will sell such allowances to the bidder(s), provided that, pursuant to § 73.70 (c)(4), the offer states the offeror's willingness to sell

fewer allowances than were offered for sale.

(e) *Announcement of results.* Following each auction, the Administrator will publish the names of winning bidders and their bids, the amounts of losing bids, and the lowest price at which allowances are sold. The Administrator will announce the results of each auction through the Allowance Tracking System. The results will also be published in the **Federal Register** and in the Commerce Business Daily.

(f) *Transfer of allowances.* Allowances will be transferred from the Auction Subaccount and from the subaccount for allowances offered by authorized account representatives to the Allowance Tracking System accounts of successful bidders as soon as payment is collected by the Administrator.

(g) *Return of Unsuccessful Bids.* The Administrator will return payment to unsuccessful bidders and to bidders unwilling to purchase fewer allowances than requested following the conclusion of each auction.

(h) *Transfer of Proceeds.* The Administrator will return all proceeds from the auction as follows:

(1) Allowances auctioned from the Auction Subaccount. Not later than 90 days following each auction, the Administrator will pay a pro rata share of the proceeds of each auction to the authorized account representative of each unit from whose annual allowance allocation allowances were withheld for the purposes of establishing the Auction Subaccount. Each unit's pro rata share will be calculated pursuant to regulations to be promulgated under subpart B.

(2) Allowances contributed from others. Not later than 90 days following each auction, the Administrator will transfer the full amount of the proceeds of each sale of allowances offered by authorized account representatives to such representatives. Proceeds from the sale of allowances that were offered with the same specified minimum price will be distributed according to each such offeror's pro rata share of the sale of such allowances.

(3) The Administrator will pay no interest on any payment made pursuant to paragraphs (h)(1) and (2) of this section.

(i) *Return of unsold allowances.* The Administrator will return all unsold allowances from the auction as follows:

(1) Allowances in the Auction Subaccount. At the conclusion of each auction, the Administrator will transfer to the Allowance Tracking System account of each unit specified in paragraph (h)(1) of this section its pro rata share of any allowances remaining in the Auction Subaccount. Each unit's pro rata share will be calculated pursuant to regulations to be promulgated under subpart B.

(2) Allowances contributed from others. At the conclusion of each auction, the Administrator will return unsold allowances to the appropriate offerors' Allowance Tracking System accounts. Any unsold allowances that were offered with the same specified minimum price will be distributed according to each such offeror's pro rata share of all such allowances offered.

§ 73.71 Bidding.

(a) *Who may participate in the auctions.* Any person may participate in the auctions by submitting a bid or bids pursuant to this section.

(b) *Bidding.* Sealed bids shall be sent to the Administrator using the Bid Form for SO_2 Allowance Auctions, or some method of electronic transfer if the Administrator, following public notice, so requires or permits at some future time. The bid form shall state:

(1) The number of allowances sought and the price;

(2) Whether spot or advance allowances are sought;

(3) Allowance Tracking System account number;

(4) Whether the bidder is willing to purchase fewer allowances than the number of allowances stated in (b)(1) of this section if the full amount is not available. Where the bidder holds no Allowance Tracking System account, a New Account/New Authorized Account Representative Form must accompany the bid. New account information shall include at a minimum: Name, address, telephone number, facsimile number, organization or company name (if applicable), type of organization, and the authorized account representative for purposes of the account.

(c) *Payment.* Each bid must include a certified check or letter of credit for the total bid price, or may specify a method of electronic transfer or other method of payment, if the Administrator, following public notice, so requires or permits at some future time. The certified check should be made payable to the U.S. EPA. To meet the requirements of this paragraph bidders must submit a completed SO_2 Allowance Auction Letter of Credit Form. If such Form is used, the Administrator must receive full payment for allowances awarded at the auctions, either by wire transfer or certified check, no later than 2 business days after the results of the auction are announced in the Allowance Tracking System.

(d) *Bid amount and number of bids.* Bidders may request any number of allowances up to the amount of allowances available for auction. Any person may submit more than one bid in each auction, provided that each bid meets the requirements of this section.

(e) *Submission of bids.* The Administrator will publish in the **Federal Register** and in the Commerce Business Daily the address of where to submit bids and payment not later than 60 calendar days before each auction.

(f) *Deadline for bids.* All bids must be revised by the Administrator no later than 3 business days prior to the date of the auctions.

§ 73.72 Direct sales.

(a) *Allowances to be sold.* The Administrator will sell allowances every year according to the following schedule:

TABLE 2.—ALLOWANCE SCHEDULE FOR THE DIRECT SALE

Year of purchase	Spot sale	Advance sale
1993		* 25,000
1994		* 25,000
1995		* 25,000
1996		* 25,000
1997		* 25,000
1998		* 25,000
1999		* 25,000
2000 and after	25,000	* 25,000

* Not useable until 7 years after purchase.

(b) *Adjustment of the direct sale schedule.* The schedule listed in paragraph (a) of this section will be adjusted to reflect allowances subject to IPP written guarantees pursuant to § 73.74.

(c) *Price.* Allowances in the direct sale will be sold at $1,500 per allowance, adjusted by the Consumer Price Index (CPI). The following formula will be used each year to calculate the price:

$$\$1500 \times [1 + CPI(year) - CPI(1990)]$$

$$CPI(1990)$$

(d) *Form and timing of the direct sale.* The Administrator will begin accepting applications for the direct sale on June 1st of each calendar year and will continue to accept applications up to 10 calendar days prior to the allowance transfer deadline.

(e) *Who may purchase from the direct sale.* Any person may apply to purchase allowances from the direct sale.

(f) *Amount allowed to purchase.* Applicants may request to purchase any number of allowances up to the amount available for sale in the Direct Sale Subaccount.

(g) *Request to purchase allowances.* Applicants shall submit the Direct Sale Application Form to request to purchase allowances from the Administrator, or shall make such request by some method of electronic transfer if the Administrator, following public notice, so requires or permits at some future time. The Direct Sale Application Form shall state:

(1) The number of allowances sought;

(2) Whether spot or advance allowances are sought;

(3) The Allowance Tracking System account number; and

(4) Whether the applicant is willing to purchase fewer allowances than the number of allowances stated in (g)(1) of this section, if the full amount is not available. Where the applicant holds no Allowance Tracking System account, a New Account/New Authorized Account Representative Form must accompany the application. New account information shall include at a minimum: name, address, telephone number, facsimile number, organization or company name (if applicable), type of organization, and the authorized account representative for purposes of the account.

(h) *Submission of direct sale applications.* The Administrator will publish in the **Federal Register** and in the Commerce Business Daily the address of where to submit Direct Sale Application Forms no later than 60 calendar days before each direct sale.

(i) *First come, first served.* Applications will be approved in order of receipt, indicated by the date and time stamped on the applications upon arrival at the destination indicated pursuant to paragraph (h) of this section.

(j) *Partial fulfillment of requests.* In the event the number of allowances requested for a purchase exceeds the number of allowances remaining in the Direct Sale Subaccount, the Administrator will approve the request for the number of allowances remaining, provided that, pursuant to paragraph (g)(4) of this section, the application states the applicant's willingness to purchase fewer allowances than the number stated in its application. In all other cases, the Administrator will place applicants on the waiting list pursuant to paragraph (n) of this section.

(k) *Notification of approval.* After approving an application, the Administrator will notify the applicant of the amount and type of allowances that may be purchased, the date on which the approval was made, the exact price of allowances for purchase from the direct sale, and instructions for making payment.

(l) *Payment.* Applicants shall submit 50% of the total purchase price by six months after the date of approval of their request to purchase. Pursuant to paragraph (m) of this section, the remaining 50% must be paid on or before the allowance transfer deadline. In the event that approval is granted less than six months prior to the allowance transfer deadline, payment shall be made on or before the allowance transfer deadline, pursuant to paragraph (m) of this section. The Administrator will terminate the approval of any request to purchase upon failure to pay the 50% deposit within six months. Upon failure to submit timely payment for the remaining balance, the Administrator will terminate the sale and the deposit will be forfeited. The 50% deposit and the final payment shall be made by certified check or by some method of electronic transfer or other instrument if the Administrator, following public notice, so requires or permits at some future time. The certified check should be made payable to the U.S. EPA.

(m) *Oversubscription payment deadline.* The Administrator will assess the status of the allowance reservations to the Direct Sale Subaccount on December 1 of each year the direct sale is held. In the event that the direct sale is oversubscribed by December 1, the Administrator will require full payment for reserved allowances no later than the oversubscription payment deadline for those applicants whose applications were previously approved and for whom allowances were reserved. Allowances will be transferred immediately upon such payment.

(n) *Oversubscription to the direct sales program.* Applications received after all allowances in the Direct Sale Subaccount are subject to approved applications shall be included on a waiting list and ranked in order of receipt, as indicated by the time and date stamped on the application upon arrival at the destination indicated pursuant to paragraph (h) of this section. In the event that an approved application is terminated pursuant to paragraph (l) of this section, applications on the waiting list will be approved according to the order in which they are ranked, subject to paragraph (i) of this section. Approved applicants will be notified pursuant to paragraph (k) of this section. If applicants without reserved allowances wish to contact those wait-listed applicants for whom allowances have been reserved, in case such applicants choose not to purchase their reserved allowances, the Administrator will make such information available upon request. Full payment for allowances must be collected by the Administrator on or before the allowance transfer deadline.

(o) *Transfer of allowances.* Allowances will be transferred to purchasers' Allowance Tracking System accounts from the Direct Sale Subaccount as soon as full payment is collected.

(p) *Transfer of proceeds.* Not later than 90 days after the conclusion of the direct sale, the Administrator will pay a pro rata share of the total proceeds of the direct sale (including forfeited deposits) to the authorized account representatives of each unit from whose annual allocation allowances are withheld for the purposes of establishing the Direct Sale Subaccount. The Administrator will pay no interest on such payment. Each unit's pro rata share will be calculated pursuant to regulations to be promulgated under subpart B of this part.

(q) *Unsold allowances in the Direct Sale Subaccount.* If allowances remain in the Direct Sale Subaccount after the allowance transfer deadline, the Administrator will transfer those allowances to the Auction Subaccount. All allowances remaining from the spot sale will be sold in the spot auction in

the following year. Advance allowances transferred from the direct sale will be sold in an additional advance auction the following year, in which allowances usable for compliance in six years will be sold. This additional auction will be conducted before allowances offered by authorized account representatives are auctioned.

§ 73.73 Delegation of auctions and sales and termination of auctions and sales.

(a) *Delegation.* The Administrator may, in the Administrator's discretion, by delegation or contract provide for the conduct of sales or auctions under the Administrator's supervision by other departments or agencies of the United States Government or by nongovernmental agencies, groups, or organizations.

(b) *Termination of sales.* If the Administrator determines that, during any period of 2 consecutive calendar years, fewer than 20 percent of the allowances available in the subaccount for direct sales have been purchased, the Administrator shall terminate the Direct Sale Subaccount and transfer such allowances to the Auction Subaccount.

(c) *Termination of auctions.* The Administrator may, in the Administrator's discretion, terminate the withholding of allowances and the auctions if the Administrator determines, that, during any period of 3 consecutive years after 2002, fewer than 20 percent of the allowances available in the Auction Subaccount have been purchased.

§ 73.74 Independent power producers written guarantee.

(a) *Nature of guarantee.* The written guarantee is a right to purchase allowances from the Direct Sale Subaccount for $1,500 (CPI adjusted) prior to the time in each calendar year that such allowances are offered for sale to others.

(b) *Issuance of a guarantee.* IPP written guarantees will be issued for a unit and not to the unit's owners and may only be transferred with the unit itself. Each guarantee application pertains to one specific unit.

(c) *Yearly total number guaranteed.* The number of allowances which may be subject to such written guarantees each year will be equal to the total number of allowances in the Direct Sales Subaccount for that year (50,000).

(d) *Duration of the guarantee.* Applicants may request a guarantee for the useful life of the unit, up to 30 years, beginning in the year 2000.

(e) *Termination of the guarantee.* The Administrator will terminate a written guarantee if the unit for which a guarantee is issued has not commenced commercial operation by January 1, 2000 or within two years of the planned start-up date of the unit, whichever is later, or if the holder of the guarantee fails to make a continuing good faith effort to obtain allowances, including participation in the annual auctions, as required under section 416(c)(4) of the Act. The Administrator will also terminate a guarantee if the holder of the guarantee fails to notify the Administrator of the continued need for the guarantee pursuant to § 73.76(e).

§ 73.75 Application for an IPP written guarantee.

(a) *Application requirements.* Applicants shall demonstrate the following by filling out the Application for an IPP Written Guarantee for SO_2 Allowances:

(1) Certification of Qualifications. Each applicant shall certify that it is the owner or operator of a new independent power production facility and that it meets the criteria set forth in the definition of new independent power production facility, and, where applicable, submit a certified statement from a senior manager (who shall meet the requirements of "certifying official" set forth in § 73.3) of its affiliate that it cannot supply all or any of the required allowances.

(2) Proof of "propose to construct" a new unit. Each applicant shall demonstrate any *one* of the following:

(i) That it has been selected as a winning bidder in a utility competitive bid solicitation;

(ii) That it has entered into a legally binding power sales agreement or such agreement has been entered into on its behalf;

(iii) That it has entered into a legally binding fuel supply agreement or such agreement has been entered into on its behalf;

(iv) That it has received a site lease or proof of land acquisition;

(v) That it has entered into a legally binding steam sales agreement or such agreement has been entered into on its behalf; or

(vi) That it has submitted a complete environmental permit application or has received such a permit.

Each applicant shall submit the relevant document in support of the demonstration. If the document is longer than 10 pages, only the signature page(s) and the first 10 pages of the document shall be submitted.

(3) Pledge to apply for financing. The applicant shall certify that it will apply for, or has applied for, financing for the unit after January 1, 1990 and before the date of the 1993 auction.

(4) Submission of written offers at $750. The applicant shall certify that it has made offers to purchase some or all of the required allowances at $750 each from all phase I utilities, but that it received no unconditional acceptances within 180 days from the date on which each offer was made.

(5) Other information required. The applicant shall submit the following information for the unit:

(i) The proposed location (complete address);

(ii) The proposed production capacity and fuel source;

(iii) Sulfur dioxide emissions limitations under which the unit will be required to operate;

(iv) Projected annual emissions of sulfur dioxide;

(v) Annual allowances requested;

(vi) The proposed date on which the unit will commence commercial operation; and

(vii) The unit's expected operating lifetime.

(b) *Application submitted after the 1993 Auction.* An application may be submitted after the date of the 1993 auctions provided that it meets all the requirements of paragraph (a) of this section and includes Supplement A of the Application For An IPP Written Guarantee For SO_2 Allowances which requests the name of the financial entity(ies) to whom application for financing was made.

(c) *Submittal location.* Completed applications shall be submitted to: U.S. Environmental Protection Agency, Acid Rain Division (ANR–445), 401 M Street, SW., Washington, DC 20460, attn.: IPP Written Guarantee.

(d) *Certification.* Certification of all requirements shall be made by a certifying official upon his/her verification of all information and documentation submitted. Changes by an applicant in the name of the certifying official must be made in writing to the Administrator.

(e) *Recordkeeping requirements.* Applicants shall maintain and make available to the Administrator, at the Administrator's request, copies of the $750 written offers to Phase I utilities, any responses to such offers, and copies of documents showing the project milestones set forth in paragraph (a)(2) of this section that have been attained. Holders of written guarantees shall retain copies of their bids in the annual auctions and any written offers made to other allowance holders and shall make such documents available to the

Administrator at the Administrator's request.

§ 73.76 Approval and exercise of the IPP written guarantee.

(a) *First come, first served.* The Administrator will process and approve or disapprove, in whole or in part, applications received on or after the effective date of the regulations. The Administrator will issue guarantees pursuant to approved applications according to the order in which applications are received, as indicated by the date and time stamped on the applications upon arrival at the destination indicated in § 73.75(c).

(b) *Oversubscription to the IPP written guarantee program.* Applications received after all allowances in the Direct Sale Subaccount have become subject to written guarantees or when there is an insufficient number of allowances available to satisfy the amount requested for any year covered by the guarantee will be included on a waiting list and ranked in order of time and date of receipt. In the event that an IPP guarantee is terminated pursuant to § 73.74(e), the Administrator will process applications on the waiting list by rank order and will issue guarantees pursuant to any approved application.

(c) *Deficient applications.* The Administrator may, in his or her discretion, return applications that fail to meet the requirements set forth in §§ 73.75 (a), and (b) if applicable. Revised applications will be processed according to the date and time of receipt of such revised applications.

(d) *Notification of approval.* The Administrator will issue a written guarantee pursuant to each approved application within 30 calendar days of receipt, provided that there is a sufficient number of allowances available to satisfy the guarantee for each year covered by the guarantee at the time the application is processed.

(e) *Certification of continued need for the guarantee.* (1) By no later than June 30 and December 31 of 1992 and no later than December 31 of each year thereafter, the certifying official for a unit for which a guarantee has been issued shall certify, through written notification, to the Administrator that the unit continues to require allowances subject to the guarantee pursuant to § 73.75.

(2) As soon as a unit for which a guarantee has been issued is no longer in need of any or all of the allowances subject to the guarantee, the certifying official shall notify the Administrator, in writing, of the number of allowances that are no longer needed. Pursuant to the terms of the notification, the Administrator will reduce the number of allowances subject to the guarantee or terminate the guarantee.

(f) *Exercise of guarantee.* Allowances may be purchased in each year for those years for which the guarantee has been issued provided that they are purchased for the unit for which the guarantee has been issued. In any year, the certifying official of a unit for which a guarantee is issued may purchase any number of allowances up to the maximum number specified in the guarantee for such year. Allowances purchased through guarantees will be fully transferable.

(1) Notification and response. To exercise a written guarantee, the certifying official shall notify the Administrator of the number of allowances to be purchased. Such notification shall be in writing and signed by the certifying official pursuant to § 73.75(d). The Administrator, following public notice, may require or permit a method or methods of electronic transfer of this information. The Administrator will respond to the written notification within 5 business days after receipt by sending the certifying official a statement of the exact price for the allowances and where to send payment. If the certifying official does not have an account in the Allowance Tracking System, the New Account/New Authorized Account Representative Form shall be completed and mailed with payment.

(2) Payment. Certifying officials shall purchase allowances by certified check for the total amount or by some method of electronic transfer or other instrument, if the Administrator, following public notice, so requires or permits at some future time. The certified check shall be made payable to U.S. EPA.

(3) Time period to exercise. Notification to exercise a guarantee shall be received by the Administrator no later than April 15th of the calendar year in which allowances are to be purchased. Payment for allowances shall be collected by the Administrator no later than May 15th of that same year. If the direct sales program has been terminated pursuant to § 73.73(b), notification and payment may occur at any time prior to the allowance transfer deadline for each year in which allowances are to be purchased.

(g) *Transfer of allowances.* Allowances will be transferred into the unit's allowance system account as soon as full payment is collected.

(h) *Transfer of proceeds.* The Administrator will pay all proceeds from the exercise of written guarantees pursuant to § 73.72(p).

§ 73.77 Relationship of the independent power producers written guarantee to the direct sale subaccount.

(a) *Reserving allowances in the Direct Sale Subaccount.* The Administrator will make available up to 50,000 yearly allowances in the direct sales subaccount for written guarantees. The Administrator will first reserve for IPP guarantees the 25,000 yearly allowances in the advance sale category. If more than 25,000 yearly allowances are subject to guarantees, the excess allowances needed will be reserved from the spot allowance category, up to 25,000 each year.

(b) *Adjustment of the direct sale schedule.* If fewer than 25,000 advance allowances are subject to written guarantees for any year from 2000 through 2006, any remaining advance allowances will be sold in the advance sale seven years preceding that year. If all 25,000 advance allowances are reserved for written guarantees for 2000 through 2006, the direct sale will begin in the year 2000 and will consist only of spot sales of allowances not sold pursuant to written guarantees.

(c) *Continuation of the guarantee.* Termination of the direct sale will not affect IPP written guarantees which will continue in effect for the operating life of the unit or 30 years, whichever is shorter, unless terminated pursuant to § 73.74(e).

(d) *Guaranteed allowances not sold.* If a certifying official of a unit for which a guarantee is issued chooses not to exercise the guarantee for a year in which allowances are reserved, the allowances will be offered for sale in the direct sale beginning on June 1 of that year. In the event the direct sale is terminated, any unsold allowances will be transferred to the Auction Subaccount pursuant to § 73.72(q).

Subpart F—Conservation and Renewable Energy Reserve [Reserved]

§§ 73.80–73.89 [Reserved]

[FR Doc. 91–29744 Filed 12–16–91; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

[FRL-4039-3]

Request for Delegation Proposals to Administer the Auctions and Direct Sale and Request for Public Comment

AGENCY: Environmental Protection Agency.

ACTION: Notice of EPA request for delegation proposals to administer the auctions and direct sale under section 416 of the Clean Air Act amendments of 1990, and request for public comment.

SUMMARY: Pursuant to title IV of the Clean Air Act Amendments of 1990 ("the Act"), the Administrator must promulgate regulations to reduce emissions of sulfur dioxide (SO_2) and nitrogen oxides (NO_x), precursors of acid rain. The centerpiece of the SO_2 control program is the allocation of transferable allowances, or authorizations to emit SO_2, which are distributed in limited quantities for existing utility units and which eventually must be held by all utility units to cover their SO_2 emissions. These allowances may be transferred among polluting sources and others, so that market forces may govern their ultimate use and distribution, resulting in the most cost-effective sharing of the emissions control burden. In order to stimulate and support such a market in allowances, and to provide a public source of allowances particularly to new units for which no allowances are allocated, the Administrator is directed under section 416 of the Act to conduct an annual sale and auctions of allowances.

Today, the Administrator promulgated regulations for conducting such sales and auctions, as well as regulations under which certain independent power producers ("IPP") may obtain written guarantees of the availability of allowances and may exercise priority in purchasing allowances through the direct sale (see 40 CFR part 73).

Along with the publication of these regulations, EPA is, in this notice: (1) Notifying the public of its intent to request proposals for the delegation of the administration of the auctions and direct sale, (and the issuance of allowances for persons holding Independent Power Producer guarantees) under the authority of section 416(f) of the Act; (2) requesting such proposals; and (3) seeking, from any member of the public, comments, with regard to this notice before deciding whether to delegate these functions. EPA reserves its discretion to decline to delegate these functions following review of proposals and comments submitted pursuant to this notice.

Delegation of these functions shall be administered without compensation from EPA. A delegatee will not be allowed to retain any portion of the monies collected for the sale or auction of allowances or to charge fees to administer these functions. In addition, the delegation will require a strict adherence to the regulations as promulgated today in 40 CFR part 73. EPA will be accepting proposals to administer these programs from candidates who meet the criteria specified in section III of this notice. Demonstration of these criteria will be made by the completion of a delegation application which will explain in more detail the evaluation criteria, the corresponding emphasis EPA places on those criteria, and procedural requirements. Delegation applications may be obtained from EPA at the address listed below.

EPA will hold a public meeting on this notice on the date listed below. The purpose of the public meeting is to explain further, and answer questions about, the objectives and requirements for the delegation.

DATES: Complete proposals, in the form of delegation applications, for undertaking administration of the auctions, direct sale, and IPP written guarantee program, and public comments, must be received, in writing, on or before February 21, 1992. Proposals and public comments should be sent to the address listed below. The public meeting on this notice will be held on January 13, 1992 from 2 p.m. to 4 p.m.

ADDRESSES: U.S. EPA Acid Rain Division (ANR-445), 401 M St., SW., Washington, DC 20460, Attn: Auctions and Direct Sale Delegation.

The public meeting will be held at the address given above in the EPA Conference Center Room 3 North.

FOR FURTHER INFORMATION CONTACT: Linda Reidt Critchfield, EPA/OAIAP/Acid Rain Division (ANR-445), 401 M St., SW., Washington, DC 20460 (202) 260-7915.

SUPPLEMENTARY INFORMATION:

I. Authority

Pursuant to section 416(f) of the Clean Air Act Amendments of 1990, the Administrator may, in his or her discretion, delegate, or contract for, the conduct of sales or auctions under the Administrator's supervision by other departments or agencies of the United States Government or by nongovernmental agencies, groups, or organizations. The Administrator is considering whether to exercise this discretion under section 416(f) and 40 CFR part 73, § 73.73(a) and to delegate the administration of the auctions, direct sale, and IPP program to the candidate determined by the Administrator to be the most qualified. The Administrator will base this determination on the public comments received and the proposals, in the form of delegation applications, submitted to meet the criteria contained in the delegation application.

II. Functions of the Delegatee in Conducting the Auctions and Direct Sale

In addition to adhering to the applicable requirements for the auctions, direct sale, and IPP program set forth in the regulations promulgated today, and summarized below, a major component in administering the auctions and direct sale would be the interaction between a delegatee's information system and EPA's Allowance Tracking System (ATS). The ATS will issue, record, and track allowances and will be the official computer system for the supply of allowances. For a complete discussion of the ATS, see subpart C (Allowance Tracking System) of the proposed Sulfur Dioxide Allowance System regulations which were published in the Federal Register on December 3, 1991.

The specific duties and the interactions between the ATS and a delegatee would be fully developed when such duties are discussed with the appointed delegatee and when Subpart C (Allowance Tracking System) of 40 CFR part 73 is promulgated. The information system used by a delegatee would need to interface with the ATS in a form compatible with the ATS format.

Listed below are the major steps in conducting the auctions, direct sale, and IPP written guarantee program, pursuant to 40 CFR part 73, subpart E. Though not included in these steps, recordkeeping and tracking functions are also required in the administration of the auctions and direct sale. Almost all the duties listed below would be carried out by a delegatee through electronic methods, unless otherwise specified.

A. Conducting the Auctions

Pursuant to 40 CFR part 73, §§ 73.70 through 73.71, a delegatee would conduct the auctions as follows:

1. The delegatee will receive notice from others offering to sell their allowances in the EPA auctions. The delegatee will notify the ATS of these contributions so that the ATS can place

them in a separate subaccount for offered allowances.

2. EPA will publish notice in the **Federal Register** and Commerce Business Daily of the date that the auctions will be held, the total number of allowances to be auctioned, including both those in the EPA Auction Subaccount and those offered by private parties, and any minimum prices specified by private parties. Information about allowances offered by private parties will be provided by the delegatee.

3. The delegatee will receive sealed auction bid forms and a prescribed form of payment from those seeking to purchase allowances in the EPA auctions. The delegatee will deposit certified checks in an EPA-specified bank account. If a letter of credit ((LOC) is submitted, the delegatee will hold the LOC until the auctions are completed.

4. The delegatee will review bid forms; if incomplete or incorrect, the delegatee will return the bid form and payment.

5. The delegatee will conduct the auctions by matching allowances and bids.

6. The delegatee will notify the ATS of the results of each auction for the purpose of transferring allowances to winning bidders' accounts and publishing the results of each auction. The delegatee will also notify the ATS of any winning bidders for whom a new account must be established.

7. Within 2 business days of publication of the auction results in the ATS, the delegatee will collect payment from winning bidders using an LOC.

8. The delegatee will deposit the total proceeds from the auctions in an EPA-specified bank account and inform the ATS of this amount.

9. EPA will publish the results of each auction in the **Federal Register** and the Commerce Business Daily.

10. The delegatee will return LOCs or send refund checks to losing bidders.

B. Conducting the Direct Sale and Fulfilling the IPP Written Guarantee

Pursuant to 40 CFR part 73, §§ 73.72 through 73.77, a delegatee would conduct the direct sale and the IPP written guarantee program as follows:

Implementing the IPP Written Guarantee

1. The delegatee will receive notification from IPPs choosing to exercise their written guarantees.

2. Not later than five business days after receipt of such notification, the delegatee will send the IPP a statement confirming the amount and type of allowances requested, the exact price, and payment instructions.

3. The delegatee will receive from IPPs, payment for the total amount of allowances they are requesting to purchase at that time.

4. The delegatee will notify the ATS of the purchases from the IPPs, and deposit all payment proceeds in an EPA-specified bank account.

Implementing the Direct Sale

1. EPA will publish in the **Federal Register** and in the Commerce Business Daily notice of the beginning and ending date of the direct sale, and the amount of allowances for sale.

2. The delegatee will receive requests to purchase allowances and notify applicants of approved requests. The delegatee will reserve requested allowances on a first come, first served basis as applications are approved. The delegatee will sent notice to approved applicants of the amounts and type of allowances reserved, the date on which approval was made, the exact price, and payment instructions. If the direct sale is oversubscribed, the delegatee will establish a waiting list.

3. The delegatee will process deposits and final payments. The delegatee will transmit to the ATS, account numbers of buyers and purchase amounts as sales are completed. The delegatee will deposit all payments in an EPA-specified bank account.

III. Criteria To Be Used in Selecting an Organization for Delegation

In exercising his or her discretion to delegate the administrations of the auctions, direct sale, and IPP written guarantee program, the Administrator would evaluate applicants based on the following criteria:

1. Ability to process and manage financial instruments such as letters of credit, certified checks, and electronic payment.

2. Knowledge of administering a sealed bid, discriminating form of auction.

3. Experience in developing and using transactional information systems and information transaction processing in commercial applications, comparable to automated bid matching program and interface with the ATS.

4. Experience developing and managing a document control system for recordkeeping and information tracking.

5. Adequate resources, staff, and facilities to meet the implementation requirements of section 416 of the Act.

6. Ability to produce summary reports and analysis of auctions and direct sale results.

7. Knowledge of the Clean Air Act title IV, Section 416 and its implementing regulations and programs.

The delegation application will include a more detailed statement of these criteria and how they will be applied to the proposals. Applicants will also be required to agree to provide the Administrator with advance notice of termination of the delegation not later than eighteen months prior to the time of termination. Applicants must also agree to provide a complete surrender of all documentation, computer software, and any other critical information associated with the administration of the auctions, direct sale, and IPP written guarantee program. Applicants will also be required to explain the linkage the delegation would have to their other on-going or planned activities or to the interests of any constituency represented by the applicant. The proposal should indicate what legitimate advantage the delegatee will derive from running the auctions, direct sale, and IPP written guarantee program.

IV. Requests for Public Comment

EPA is seeking to delegate the administration of the auctions, direct sale, and IPP written guarantee program for a variety of reasons. EPA has heard from the Acid Rain Advisory Committee (ARAC), utilities, and others, concerns about a government agency such as EPA, with no experience in conducting auctions, administering such functions. This concern was voiced even prior to enactment and is reflected by language in the Act that gives EPA broad discretion to delegate or contract out these functions. As an alternative to EPA administering these functions, EPA explored various options for administering the auctions and direct sales, including other Federal Agencies and Departments, and contracts.

EPA therefore requests comment from the public on the option for delegating the functions described in this notice to a private entity. Such comments will be considered in the review of individual proposals and EPA's decision whether to delegate this program.

Dated: December 4, 1991.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

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December 17, 1991

Part IV

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 761 et al.

Intial and Permanent Regulatory Programs: Special Categories of Mining; Surface and Underground Mining Activities; Final Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 761, 780, 784, 785, 816 and 817

RIN 1029-AA57

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Areas Unsuitable for Mining; Special Categories of Mining; Surface Mining Activities; Underground Mining Activities

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the U.S. Department of the Interior (DOI) is amending its permanent program permitting and performance standards regulations in several technical areas. The technical areas affected are (1) Backfilling and grading, (2) Approximate original contour (AOC) variances, (3) Disposal of coal mine waste, (4) Definition of values incompatible with surface coal mining operations, (5) Disposal of excess spoil on preexisting benches, and (6) Contemporaneous reclamation practices. Except for the area of disposal of excess spoil on preexisting benches, the amendments are in response to U.S. District Court and Court of Appeals decisions.

In the area of values incompatible with surface coal mining operations, the rule amends the definition of "no significant recreational, timber, economic, or other values incompatible with surface coal mining operations" to eliminate reclaimability as a criterion in determining compatibility with surface coal mining operations.

In the area of AOC variances, the rule revises regulations governing permits incorporating variances from AOC restoration requirements to limit their application to steep slope mining.

In the area of disposal of excess spoil on preexisting benches, the rule revises special regulations governing the disposal of excess spoil on preexisting benches for conformance with OSM's generic backfilling and grading regulations. OSM is revising the rules to encourage the reclamation of abandoned highwalls by removing impediments to the use of excess spoil on preexisting benches.

In the area of disposal of coal mine waste, the rule revises former requirements for the disposal of coal mine waste by adding the requirement that coal mine waste be hauled or conveyed for final placement to the point of disposal. This addition prohibits the final placement of coal mine waste by end or side dumping in any area other than mine workings and excavations. The rule also removes regulatory language cross-referencing the requirements for handling of hazardous noncoal coal mine waste in accordance with the Environmental Protection Agency's (EPA's) Resource Conservation and Recovery Act (RCRA) and its implementing regulations.

In the areas of contemporaneous reclamation and backfilling and grading, the final rule reestablishes backfilling and grading time and distance requirements. The rules require the completion of backfilling and grading within certain times or distances following coal removal, or, for mining methods other than area and contour mining under a schedule established by the regulatory authority, or under case by case time and distance variances approved by the regulatory authority. Also in the context of backfilling and grading to AOC, the rules define "thin overburden" and "thick overburden", and establish performance standards for backfilling and grading in areas of thin and thick overburden.

Finally, existing suspensions of previous regulations are removed where they are superseded by these final regulations.

EFFECTIVE DATE: January 16, 1992.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis M. Hunter, Jr., Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Ave. NW, Washington, DC 20240.

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion of Final Rule and Comments
III. Procedural Matters

I. Background

These rules amend several technical areas in 30 CFR, chapter VII. These areas have been combined in this rulemaking for administrative convenience. Therefore, the pertinent legislative, regulatory and litigation background for each technical area is discussed separately below.

Where the discussion concerns similarly or identically constructed sections in part 816, which applies to surface mining activities, and part 817, which applies to underground mining activities, these sections are cited together in the heading as §§ 816. [ ] and 817. [ ]. In such cases the subsequent discussion, while only referring to § 816. [ ], nevertheless applies identically to both parts 816 and 817 unless otherwise noted.

A. Section 761.5 Values Incompatible with Surface Coal Mining Operations

Section 522(e)(2) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), 30 U.S.C. 1272(e)(2), with certain exceptions, prohibits surface coal mining operations

> on any Federal lands within the boundaries of any national forest [unless] the Secretary finds that there are no significant recreational, timber, economic, or other values which may be incompatible with such surface [coal] mining operations * * *.

The corresponding OSM permanent program regulation appears at 30 CFR 761.11(b).

In implementing this requirement, the 1979 OSM regulations at 30 CFR 761.5 defined the emphasized language in section 522(e)(2) in part to mean:

> [T]hose significant values which could be damaged by, and are not capable of existing together with, surface coal mining operations because of the undesirable effects mining would have on those values, either on the area included in the permit application or on off-site areas which could be affected by mining * * *. (44 FR 15341, March 13, 1979).

On June 10, 1982 (47 FR 25278) OSM proposed, and on September 14, 1983 (48 FR 41312) OSM promulgated, a rule revising the 1979 definition. The revised definition dropped the introductory term "no" as unneccessary, changed the phrase "significant values" to "values to be evaluated for their significance," changed the term "offsite areas which could be affected by mining" to "affected areas," and of particular relevance to this proposed rule, inserted after the word "damage" the phrase "beyond an operator's ability to repair or restore."

Thus, following revision in 1983, the corresponding portion of the definition read:

> Significant recreational, timber, economic, or other values incompatible with surface coal mining operations means those values to be evaluated for their significance which could be damaged beyond an operator's ability to repair or restore by, and are not capable of existing together with, surface coal mining operations because of the undesirable effects mining would have on those values, either on the area included in the permit application or on other affected areas. 30 CFR 761.5 (1983).

This revised definition was challenged by the citizen and environmental plaintiffs in In re Permanent Surface Mining Regulation Litigation (In re Permanent II (Round III)), 620 F. Supp. 1519 at 1556–57 (D.D.C. July 15, 1985). The challengers contended that the definition was contrary to the Act

because under it mining could be permitted in national forests as long as reclamation was possible. The U.S. District Court for the District of Columbia agreed with this contention and remanded the definition. *Id.* at 1557. On November 20, 1986, (51 FR 41952) OSM suspended the definition "insofar as the listed values are evaluated for compatibility solely in terms of reclaimability." *Id.* at 41960–41961.

OSM appealed, and the U.S. Court of Appeals for the District of Columbia Circuit affirmed the district court ruling. *National Wildlife Federation (NWF)* v. *Hodel*, 839 F. 2d 694, 751–53 (D.C. Cir. 1988). Like the district court, the court of appeals ruled that the revised regulation was contrary to the intent of the Congress and to elementary principles of statutory construction.

On October 31, 1988 (53 FR 43970), OSM proposed to revise the § 761.5 definition of "no significant recreational, timber, economic, or other values incompatible with surface coal mining operations" in conformance with the district court and court of appeals decisions.

B. Sections 785.16, 816.133(d), and 817.133(d)—AOC Variances

Section 515(b)(3) of the Act, 30 U.S.C. 1265(b)(3), generally requires

> * * * all surface coal mining and reclamation operations [to] backfill, compact (where advisable to insure stability or prevent leaching of toxic materials), and grade in order to restore the approximate original contour of the land with all highwalls, spoil piles, and depressions eliminated (unless small depressions are needed in order to retain moisture to assist revegetation or as otherwise authorized pursuant to this Act).

For steep slope mining, section 515(d)(2), 30 U.S.C. 1265(d)(2), imposes an additional requirement for

> [c]omplete backfilling with spoil material * * * to cover completely the highwall and return the site to the approximate original contour * * *.

The term "approximate original contour", as used in these sections, is defined in section 701(2) of the Act, 30 U.S.C. 1291(2), and in the regulations at 30 CFR 701.5 as "that surface configuration achieved by backfilling and grading of the mined area so that the reclaimed area, including any terracing or access roads, closely resembles the general surface configuration of the land prior to mining and blends into and complements the drainage pattern of the surrounding terrain * * *."

Sections 515(e)(1) through (e)(6) of the Act, 30 U.S.C. 1265(e)(1) through (e)(6), allow regulatory authorities to permit variances from AOC under certain circumstances. Section 515(e)(1) allows State regulatory programs, and requires Federal regulatory programs, to include procedures for permitting variances for the purposes set forth in section 515(e)(3). Section 515(e)(2) explicitly allows the regulatory authority to grant a variance from the steep-slope requirement of section 515(d)(2).

Accordingly, on March 13, 1979 (44 FR 15372), OSM promulgated at 30 CFR 785.16 a regulation which authorized the regulatory authority to grant a variance, when certain specified conditions were met, from AOC for steep slope mining which does not involve mountaintop removal. This regulation was challenged by the coal industry in In re Permanent Surface Mining Regulation Litigation (In re Permanent I), No. 79–1144, slip op. at 69–70 (D.D.C. February 26, 1980), as unduly restrictive.

In upholding the § 785.16 limitation of AOC variances to steep slope mining, the U.S. District Court for the District of Columbia in *In re Permanent I* said:

> Section 515(e) of the Act contains one variance provision: it applies to steep slopes. Rather than calling for a general variance mechanism, section 515(e)(1) establishes the right to apply for a variance * * *. Section 514(e)(2) restricts the variance application to the contour restoration requirements of subsection 515(d)(2) (steep slopes). Whatever ambiguity may be read into section 515 is dispelled upon examination of the legislative history. *Id.* at 69–70.

Subseqently, OSM reconsidered the legislative history of the Act and concluded "that the section allowing for AOC variances was not limited to steep slope operations." (48 FR 39900, September 1, 1983) Accordingly, OSM expanded the coverage of § 785.16 to permit variances from AOC on both steep and non-steep slope terrain, (48 FR 39892, September 1, 1983) as amended at (48 FR 44780, September 30, 1983). At the same time (48 FR 39892, September 1, 1983) OSM revised its regulations governing postmining land use to include at 30 CFR 816.133(d) criteria for permitting variances in accordance with revised § 785.16. OSM set out its rationale for these revisions in a detailed analysis of the legislative history of section 515(e), and of the issues considered by the district court in In re Permanent I, (48 FR 39899–900, September 1, 1983).

These revised regulations were challenged by the citizen and environmental plaintiffs in In re Permanent II (Round III), 620 F. Supp. at 1574–78. In response, the district court remanded the revised regulations "as inconsistent with law to the extent they permit[ted] a variance beyond the variance for steep slopes embodied in 515(e)(2) [of the Act]." *Id.* at 1577–78.

On November 20, 1986 (51 FR 41952), OSM suspended §§ 785.16 and 816.133(d) insofar as they authorized any variance from AOC outside a steep slope area. The district court remand was appealed by the coal industry, and affirmed by the court of appeals in *NWF* v. *Hodel*, 839 F.2d at 761–64. In affirming the district court, the court of appeals "rel[ied] on the text of sec. 515(e)(2), which specifically states that variances may be granted from the AOC requirements of section 515(d)(2), the steep slope mining provision; it does not, as enacted, state that non-steep slope mining AOC requirements may be waived or excused, and neither does it reference section 515(b)(3), the general AOC provision." *Id.* at 763. The court of appeals found nothing in the legislative history that would change its reading of section 515(e). *Id.* at 764.

On October 31, 1988, OSM proposed to revise § 785.16, and to remove the suspension of that section and of §§ 816.133(d) and 817.133(d), in conformance with the district court and court of appeals decisions (53 FR 43970).

C. Sections 816.74 and 817.74—Disposal of Excess Spoil on Preexisting Benches

Section 515(b)(22) of the Act, 30 U.S.C. 1265(b)(22), specifies the performance standards for disposing of excess spoil from surface coal mining and reclamation activities. Section 516(b)(10) of the Act, 30 U.S.C. 1266(b)(10), provides similar performance standards for underground mining activities.

OSM implements these statutory performance standards at 30 CFR 816.71 through 816.74 for surface mining activities and 30 CFR 817.71 through 817.74 for underground mining activities. Section 816.74 and § 817.74, which are affected by this rule, govern the disposal of excess spoil on preexisting benches.

The 1979 OSM permanent program rules did not specifically provide for the disposal of excess spoil on preexisting benches. Regulations to allow the disposal of excess spoil on preexisting benches were originally proposed by OSM on May 16, 1980 (45 FR 32331). As a result of public comment, these regulations were reproposed in substantially different form on July 20, 1981 (46 FR 37283). Final regulations were issued on April 29, 1982 (47 FR 18553), as 30 CFR 816.75.

On June 8, 1982 (47 FR 24954), as part of an overall revision of its excess spoil regulations, OSM proposed to revise § 816.75. The revised (and renumbered) regulations were promulgated on July 29, 1983 (48 FR 32910), as 30 CFR 816.74.

Paragraphs (a) through (d) of these rules were essentially the same as the 1982 regulations. A new paragraph, (e), was added to allow the disposal of excess spoil from an upper, actively-mined bench to a lower, preexisting bench by means of gravity transport in certain circumstances.

In July 1986, OSM released a study titled, "Encouraging Abandoned Mine Reclamation Via Remining: A Federal, State and Industry Initiative" for public review and comment. On September 23, 1986, OSM held a public meeting in Washington, DC, to discuss the study's proposed initiatives. Copies of the study and a transcript of the public meeting have been placed in the administrative record for this rule.

One of the initiatives proposed in the study and discussed at the public meeting was "Reclaiming Abandoned Mine Lands with Excess Spoil." Included under this proposal was the disposal of excess spoil on preexisting benches, and, particularly, whether the requirements for such disposal were excessive as compared to the requirements for backfilling and grading. Both in written comments and at the public meeting, commenters pointed out that the differences in the rules were inconsistent with the similarity in topography, geology, and physical and engineering characteristics between preexisting and actively mined benches.

On October 31, 1988, OSM proposed revisions to §§ 816.74 and 817.74 to conform their requirements with the backfilling and grading requirements of §§ 816.102 and 817.102 (53 FR 43970).

D. Sections 816.81, 816.89, 817.81, and 817.89—Disposal of Coal Mine Waste

Recognizing the problems posed by improper disposal of coal waste, the Congress included in the Act a number of performance standards governing waste disposal. These performance standards appear in section 515 of the Act, 30 U.S.C. 1265, for surface mining activities, and in section 516 of the Act, 30 U.S.C. 1266, for underground mining activities.

To implement these statutory performance standards, the 1979 permanent program included at 30 CFR 701.5 a definition of "coal processing waste", and at 30 CFR 816.81 to 816.93 (44 FR 15395 and 15422, March 13, 1979), regulations governing the disposal of coal mine waste. Several changes in the 1979 regulations, which are not relevant to this discussion but are noted for completeness, were made on August 18, 1980 (45 FR 54753), and on November 20, 1980 (45 FR 76932).

On September 26, 1983 (48 FR 44006), OSM promulgated at 30 CFR 701.5 a revised definition of "coal processing waste", and new definitions of "coal mine waste", "impounding structure", and "refuse pile". At the same time (48 FR 44006), OSM promulgated at 30 CFR 816.81, 816.83, 816.84, 816.87 and 816.89, a comprehensive revision of the 1979 regulations. These new regulations were challenged in In re Permanent II (Round III). 620 F. Supp. at 1534–38.

In re Permanent II (Round III) involved two coal waste issues that are dealt with in this rulemaking: (1) Controlled transport of coal waste; and (2) Environmental Protection Agency (EPA) regulations on hazardous wastes.

1. Sections 816.81(a) and 817.81(a)—Controlled Transport of Coal Waste

In In re Permanent II (Round III) the district court rejected §§ 816.81(a) and 817.81(a) as arbitrary and capricious to the extent they allowed end or side dumping of coal mine waste, a mining practice in "hill and valley" topographic areas of placing material at a disposal site by means of gravity. 620 F. Supp. at 1534–35.

On November 20, 1986 (51 FR 41952), OSM suspended §§ 816.81(a) and 817.81(a) insofar as they allowed end or side dumping of coal mine waste. On October 31, 1988 (53 FR 43970), OSM proposed to amend these sections by prohibiting end or side dumping of coal mine waste in regard to final placement disposal, and to simultaneously remove the suspension of the earlier version in conformance with the district court decision.

2. Sections 816.89(d) and 817.89(d)—EPA Regulations on Hazardous Wastes

Section 816.89(d) of the 1983 regulations required that "any noncoal [coal] mine waste defined as 'hazardous' under section 3001 of the Resource Conservation and Recovery Act (RCRA) (Pub. L. 94–580, as amended) and 40 CFR part 261 shall be handled in accordance with the requirements of subtitle C of RCRA and any implementing regulations." (48 FR 44006, 44030 and 44032, September 26, 1983.) As OSM noted in the preamble to the final rule, this was done at the suggestion of the U.S. Environmental Protection Agency (EPA). *Id.* at 44027.

In In re Permanent II (Round III), 620 F. Supp. at 1538, the coal industry challenged this section of the regulations, which the district court remanded for lack of adequate notice and comment. The district court said:

> Industry challenges this rule because it contends that Congress gave the Secretary exclusive responsibility to regulate every kind of waste at coal mines in SMCRA permits, and expressly provided that EPA's regulations for hazardous wastes under RCRA shall not be applied to coal mines.
>
> The court need not spend much time detailing the statutory analysis because it concludes that the rule was promulgated without adequate notice and comment under the APA [(Administrative Procedure Act)] * * *.
>
> The Secretary * * * did not respond to the Industry's APA challenge, but instead attempted to explain that the rule neither broadens nor diminishes the Secretary's rules on the disposal of noncoal [coal mine] waste. Industry takes a vastly different view of the effect of the regulation, and makes a lengthy argument that has nowhere been considered by the Secretary prior to this litigation. Second, Industry is able to point to legal and practical complications that result from the rules. *Id.*

On November 20, 1986 (51 FR 41952), OSM suspended §§ 816.89(d) and 817.89(d). OSM proposed to remove these sections from its regulations on October 31, 1988 (53 FR 43970).

E. Sections 816.100, 816.101, 816.104(a) and 816.105(a)—Contemporaneous Reclamation and Backfilling and Grading

Section 515(b)(16) of the Act, 30 U.S.C. 1265(b)(16), provides for general performance standards to require surface coal mining and reclamation operations to "insure that all reclamation efforts proceed in an environmentally sound manner and as contemporaneously as practicable with the surface coal mining operations."

In addition, section 515(b)(3) of the Act, 30 U.S.C. 1265(b)(3), with two exemptions, provides for general performance standards requiring that "all surface coal mining operations backfill, compact (where advisable to insure stability or to prevent leaching of toxic materials), and grade in order to restore the approximate original contour of the land with all highwalls, spoil piles, and depressions eliminated (unless small depressions are needed in order to retain moisture to assist revegetation or as otherwise authorized pursuant to this Act)."

As described under heading B., above, the phrase "approximate original contour" is defined as "that surface configuration achieved by backfilling and grading of the mined area so that the reclaimed area, including any terracing or access roads, closely resembles the general surface configuration of the land prior to mining and blends into and complements the drainage pattern of the surrounding terrain * * *."

The previously noted exemptions to the AOC restoration requirements of section 515(b)(3) pertain to operations

involving either "thin" or "thick" overburden. With respect to thin overburden, section 515(b)(3) provides

[t]hat in surface coal mining which is carried out at the same location over a substantial period of time where the operation transects the coal deposit, and the thickness of the coal deposits relative to the volume of the overburden is large and where the operator demonstrates that the overburden and other spoil and waste materials at a particular point in the permit area or otherwise available from the entire permit area is insufficient, giving due consideration to volumetric expansion, to restore the approximate original contour, the operator, at a minimum, shall backfill, grade, and compact (where advisable) using all available overburden and other spoil and waste materials to attain the lowest practicable grade but not more than the angle of repose, to provide adequate drainage and to cover all acid-forming and other toxic materials, in order to achieve an ecologically sound land use compatible with the surrounding region.

With respect to thick overburden, section 515(b)(3) provides

[t]hat in surface coal mining where the volume of overburden is large relative to the thickness of the coal deposit and where the operator demonstrates that due to volumetric expansion the amount of overburden and other spoil and waste materials removed in the course of the mining operations is more than sufficient to restore the approximate original contour, the operator shall after restoring the approximate contour, backfill, grade, and compact (where advisable) the excess overburden and other spoil and waste materials to attain the lowest grade but not more than the angle of respose, and to cover all acid-forming, and other toxic materials, in order to achieve an ecologically sound land use compatible with the surrounding region and that such overburden or spoil shall be shaped and graded in such a way as to prevent slides, erosion, and water pollution and is revegetated in accordance with the requirements of this Act.

The OSM permanent program promulgated on March 13, 1979 included regulations governing contemporaneous reclamation for surface mining activities at 30 CFR 816.100 (44 FR 15411), and backfilling and grading at 30 CFR 816.101, 816.102, 816.104 and 816.105 (44 FR 15411–13. Section 816.100 required reclamation efforts to occur as contemporaneously as practicable with mining operations. Section 816.101 provided time and distance schedules as general requirements for backfilling and grading. Sections 816.104 and 816.105 provided for the thin and thick overburden exemptions authorized by section 515(b)(3) of the Act.

On May 24, 1983 (48 FR 23356), OSM revised its regulations governing contemporaneous reclamation and backfilling and grading. The revision deleted § 816.101 from the regulations, and added to § 816.100 a provision authorizing regulatory authorities to establish schedules for defining contemporaneous reclamation. At the same time the numerical limits on thin and thick overburden that appeared in §§ 816.104 and 816.105, *i.e.*, plus or minus twenty percent, were deleted (48 FR 23355, May 24, 1983).

The 1983 regulations were challenged in In re Permanent Surface Mining Regulation (In re Permanent II (Round II)), 21 ERC 1724, 1744–1746 (D.D.C. October 1, 1984). As a result, the U.S. District Court for the District of Columbia remanded the regulations governing contemporaneous reclamation (§ 816.100; 21 ERC at 1745–46), cut and fill terraces (§ 816.102(g); 21 ERC 1744–45), thin overburden (§ 816.104(a); 21 ERC at 1746), and thick overburden (§ 816.105(a); 21 ERC at 1746). Generally, the district court found that the remanded regulations lacked sufficient guidance to regulatory authorities beyond what was provided in the Act.

OSM appealed the district court ruling, and the court of appeals in *NWF v. Hodel* affirmed the remand with respect to contemporaneous reclamation and thin and thick overburden, but reversed with respect to cut and fill terraces. 839 F.2d at 734–739. The court of appeals said:

We hold, in accord with the Secretary, that the Act does not automatically and inevitably *require* him to 'flesh out' the prescriptions of sections 515(b)(3) and (b)(16). Nonetheless, we affirm the remand of the contemporaneous reclamation and thick and thin overburden regulations, for only with respect to terracing did the Secretary adequately explain why guidance beyond the statutory requiremetns sensibly could not be given to local regulators.

We note that the Act expressly commands the Secretary to flesh out certain statutory provisions * * *. Nothing in the Act, however, expressly requires the Secretary to flesh out Sections 515(b)(3) or (b)(16). *Id.* at 734. (Emphasis in original).

"In short," the court of appeals continued,

we read the Act, in light of its legislative history * * * to afford the Secretary discretion, absent an express statutory instruction to regulate, to decide whether fleshing out is appropriate in light of other concerns. Chief among those concerns is the need to accommodate widely varying local conditions that will not admit of a single, nationwide rule * * *. *Id.* at 735. (Footnote omitted).

* * *Under *[Motor Vehicle Mfrs. Ass'n* v.*] State Farm [Mut. Auto. Inc. Co.,* 463 U.S. 29, 43 (1983),] 'the agency must examine the relevant data and articulate a satisfactory explanation' for the revised regulations * * *. The Secretary's accounting for his actions regarding the contemporaneous reclamation, and thin and thick overburden regulations fails to meet this standard; we do not find in the rulemaking record any identified factual basis for, or satisfactory explanation of, the Secretary's conclusion that the variety of local conditions warrants regulations on these matters that simply reiterate the relevant prescriptions in sections 515(b)(3) and (b)(16) of the Act. In contrast, we find that the Secretary adequately explained his revision of the terracing regulation. *Id.* at 735.

In affirming the district court remand of the contemporaneous reclamation regulations, the court of appeals said:

Section 515(b)(16) of the Act directs mine operators to reclaim land 'as contemporaneously as practicable [to the] mining operations.' In 1979, the Secretary had issued both a general instruction that reclamation occur 'as contemporaneously as practicable with mining operations,' 30 CFR 816.100 (1982), and specific 'time and distance' standards for backfilling and grading spoil at contour and area strip mines, 30 CFR 816.101 (1982). *Id* (Footnotes omitted, brackets in original).

The 1983 revision retained the general prescription in § 816.100, but eliminated § 816.101 entirely * * *. To support his deletion, the Secretary commented 'that "contemporaneous reclamation" is a relative term which must be interpreted by each State on the basis of the mining conditions in its territory.' * * * Because § 816.101 was devised to account for local differences, we do not find entirely satisfying, as an explanation for scrapping the regulations entirely, the observation that ' "contemporaneous reclamation" is a relative term' whose precise meaning depends on local conditions. The core deficiency, however, is that the Secretary has published barely more than a *conclusion* that the variety of mining conditions across the nation made § 816.101 of the regulations infeasible. State Farm requires a 'satisfactory *explanation*,' one that informs us *why* he drew his conclusion. The Secretary, in other words, if he determines there is no need to 'flesh out' the statute, must 'flesh out' his explanation so that we can review the rationality of his decision. *Id* at 736. (Footnote omitted, emphasis in original).

In affirming the district court remand of the thin and thick overburden regulations, the court of appeals said:

Section 515(b)(3) of the Act directs mine operators to return land to its 'approximate original contour.' The provision contains an exemption, however, for situations where the spoil is either so thin or thick relative to the coal seam that there is insufficient or too much spoil to permit return to approximate original contour.* * * In 1979, the Secretary issued regulations that defined numerically when a variance from the approximate original contour requirement for too little or too much spoil could be granted. 30 CFR 816.104 and 816.105 (1982).

In 1983, the Secretary eliminated the numerical definition, permitting a variance whenever the mine operator demonstrates that spoil is either 'insufficient' or 'more than sufficient' to restore land to its approximate

original contour. 30 CFR 816.104 and 816.105 (1986). The sole support we have found for this revision is the Secretary's cryptic observation that '[t]he mathematical limit * * * has proved to be impractical because of its preciseness.' * * * We do not know from this unadorned statement why no adjusted (less precise) or alternate nationwide rule was ordered in place of the one found impractical. Absent fuller statement of the reason for the revision, we cannot intelligently determine whether the Secretary has a 'satisfactory explanation' for his action. *Id.* at 736–737. (Footnotes omitted, brackets in original).

OSM proposed to amend §§ 816.100, 816.104 and 816.105, and to add a new § 816.101, on October 31, 1988 (53 FR 43970), in conformance with the district court and court of appeals decisions.

II. Discussion of Final Rule and Comments

A. General Comments

One commenter requested a 60-day time extension to the comment period in order to allow adequate time to evaluate the nationwide effects of the proposed regulations. The comment period originally was scheduled to end on December 30, 1988. OSM acceded in part to this request by granting an extension of the comment period by 30 days. The extended comment period closed January 30, 1989 (53 FR 52433, December 28, 1988). OSM believes that this extension of time was adequate to meet the needs of the reviewers.

B. Section 761.5 Definitions: Significant Recreational, Timber, Economic, or Other Values Incompatible with Surface Coal Mining Operations

The definition of "significant recreational, timber, economic, or other values incompatible with surface coal mining operations" in final § 761.5 was not changed from that in the proposed rule. In response to the court of appeals decision upholding the district court remand of this definition (see related discussion in I. Background, under the heading A. Values Incompatible with Surface Coal Mining Operations), OSM has amended § 761.5 to eliminate the phrase "beyond an operators ability to repair." In accordance with the courts' decisions, an operator's ability to reclaim the land may no longer be used as criterion for determining compatibility under this definition.

One commenter supported the deletion or reclaimability as required by section 522(e)(2) of the Act and court decisions. The commenter cautioned OSM against making further changes to this rule without providing for public comment. OSM thanks the commenter for submitting the cautionary remark. No changes have been made by OSM to § 761.5 following its proposal of October 31, 1988.

C. Section 785.16 Permits Incorporating Variances from AOC: Restoration Requirements for Steep Slope Mining

[Note: For related rulemaking, the reader is directed to heading J., entitled Sections 816.133 and 817.133—AOC Variances]

1. Section Heading

This section heading for § 785.16 has been revised as proposed by adding the phrase "for steep slope mining". The heading reads:

Section 785.16 Permits incorporating variances from approximate original contour restoration requirements for steep slope mining.

The revision is made to emphasize that variances from approximate original contour are authorized only for steep slope surface coal mining and reclamation operations.

2. Section 785.16(a)

Final § 785.16(a) limits the granting of AOC variances to "steep slope, surface coal mining and reclamation operations." The quoted phrase duplicates the corresponding wording of the 1979 regulation and is unchanged from the proposed rule. The November 20, 1986, suspension of § 785.16 which prevented the variance from being applied in non steep slope areas is removed. The variance is itself now limited to steep slope areas.

The language in final § 785.16(a) has been revised from the October 31, 1988 proposed language by adding a cross-reference to § 816.105. This change was made in response to a comment as discussed below.

Thick Overburden

A commenter recommended that § 785.16(a) include a reference to § 816.105, Backfilling and grading: Thick overburden, along with existing references to §§ 816.102, 816.104, 816.107, 817.102 and 817.107 because § 816.105 contains the requirement that not less than AOC be achieved during backfilling and grading in thick overburden situations.

The cross-reference to § 816.105 at § 785.16(a) was inadvertently omitted from the October 31, 1988 proposed rule through a typographical error. A correction to the proposed rule was published (54 FR 19632, May 8, 1989), and the cross-reference to § 816.105 is restored in the final rule.

Restriction to Steep Slope Areas

A commenter stated that the proposed AOC and thin overburden rules do not account for coal operations in which the overburden is composed in part of noncoal economic minerals which are removed prior to coal extraction. In such cases, according to the commenter, insufficient spoil may remain with which to return to AOC. The commenter asserted that section 515(e)(1) of the Act does not restrict the granting of AOC variances to steep slope areas, and imposing that restriction is contrary to the purpose of the Act.

Contrary to the commenter's assertion that section 515(e)(1) of the Act does not limit AOC variances to steep slope areas, the Federal courts have consistently ruled that this section limits AOC variances to steep slope areas (see discussion at I. Background, under heading B. Sections 785.16, 816.133(d), and 817.133(d)—AOC Variances). OSM will discuss the relationship between thin overburden and recovery of noncoal minerals in the section of this preamble that discusses the thin overburden exemption.

Small Depressions

A western commenter suggested that the scope of AOC variances be expanded in non steep slope areas to include small depressions needed to retain moisture for reclamation or approved postmining land uses such as livestock production which were felt to be authorized by section 515(b)(3). The commenter claimed that the alternative to such depressions is the construction of impoundments through the use of earthern dams and that such construction is not as cost effective or beneficial as depression development and increases the potential both for erosion on constructed slopes and spillways and for dam failure.

As previously noted, the courts have interpreted the provisions of section 515(e) of the Act as restricting AOC variances to steep slope areas. A discussion of the small depressions authorized by section 515(b)(3) is not germane to this rulemaking.

Effects on State Programs and Permitted Operations

The same commenter asserted that limiting variances from AOC to steep slope areas without regard to depression development would threaten the effectiveness of his State reclamation program.

In response to this concern, OSM reviewed the commenter's State program's amendment history. OSM found that the State did not have an approved program amendment which corresponded to previous § 785.16 that allowed variances from AOC for non-

steep slope areas. Accordingly, limiting variances from AOC to steep slope areas should not adversely affect that program.

Another commenter requested that OSM clarify in the final rule that § 785.16 applies prospectively to operations applying for a permit as of the date a State adopts the rule in their program. The commenter pointed out that, in light of prior OSM regulations authorizing variances from AOC for non-steep slope areas, it would be unjust to apply the final rule retroactively to operations which had previously obtained such variances.

OSM cannot agree with the commenter's recommendation that the final rule be applied prospectively. As previously discussed, in I. Background B. Sections 785.16, 816.133(d), and 817.133(d)—AOC Variances, the district and appeals courts have held that the Act restricts the AOC variance provisions of 515(e) to steep slopes. Thus, OSM has no discretion on the issue as to whether to apply the rule prospectively. On two previous occasions, OSM attempted to implement court decisions prospectively. Both attempts were overturned. *NWF* v. *Lujan*, Nos. 87–1051, 87–1814, and 88–2768, slip op. at 35–51 (D.C.C. February 12, 1990).

OSM further believes the commenter overestimates the impact the final rule will have on the coal industry. Previous § 785.16, which authorized variances from the AOC requirement in non-steep slope areas, was not approved as an amendment to any State program between its promulgation on September 1, 1983, and its suspension by OSM on November 20, 1986.

From the time of promulgation of the previous rule on September 1, 1983 through its suspension on November 20, 1986, that rule was under legal challenge. Even if operators somehow relied upon variances granted under the 1983 rule, there can be little equity in relying upon a position not justified by statute, particularly when such position is contrary to a prior rule upheld by the courts as correctly interpreting the statute. Therefore, in the light of the 1985 district court remand of the 1983 rule as inconsistent with the Act to the extent that they permitted AOC variances in non-steep slope areas, OSM has no legal alternative but to revoke such variances.

D. Sections 816.74 and 817.74 Disposal of Excess Spoil: Preexisting Benches

OSM is revising § 816.74 to conform the requirements for the disposal of excess spoil on preexisting benches with the backfilling and grading requirements of § 816.102 within the framework allowed by section 515(b)(22) of the Act. This action was prompted by public comment to an OSM study on remining initiatives and at a related public meeting. (See related discussion in II. Background, under the heading, C. Disposal of Excess Spoil on Preexisting Benches.)

Comments to the proposed rule suggested that the proposal did not meet the minimum requirements of the Act contained in section 515(b)(22) governing the disposal of excess spoil. In substituting the backfilling and grading sections for the excess spoil disposal references in § 816.74(a), several provisions required by the Act for disposal of excess spoil that do not have counterparts in the backfilling and grading regulations had to be restored. In preparing the final rule, many of those provisions which were formerly invoked through the cross reference to § 816.71 have now been specifically included in § 816.74.

OSM has maintained the principle of utilizing the backfilling and grading requirements wherever possible because preexisting benches are similar to active mining benches in the regulator controls required. The final rules contain no new regulatory requirements beyond the proposal. In some cases, as will be discussed later, proposed changes are being withdrawn because they could not be accommodated under current law.

Final § 816.74 contains 7 paragraphs. Paragraphs (a) and (b), with one exception, are being issued as they were proposed. Final paragraph 816.74 (c) is the result of combining former paragraphs (b) and (c) with certain requirements from formerly cross-referenced provisions of 816.71 which had been proposed to be deleted but are being retained. Proposed paragraph (e) is being issued as paragraph (d) with one change in addition to the paragraph designation. Final paragraphs (e), (f), and (g) have been added to § 816.74 to account for provisions in 816.71 which do not have counterparts in § 816.102. Final paragraph (h) is former paragraph (e) which has been redesignated.

Table 1 contains a cross reference which shows the derivation of each section of the new final rules. This table also contains a column which shows where the change is explained.

TABLE 1.—CROSS REFERENCE, FORMER PROVISIONS VS NEW PROVISIONS, DISPOSAL OF EXCESS SPOIL ON PREEXISTING BENCHES

Former provision	New provision	Section where change is discussed
816.71(a)	816.74(a)	816.74(a)
816.71(a)(1)	816.102(f)	816.74(a)
816.71(a)(2)	816.102(c) and 816.74(c)	816.74(a) and 816.74(c)
816.71(a)(3)	816.74(g)	816.74(g)
816.71(b)(1)	816.74(c)	816.74(c)
816.71(d)	Deleted	816.74(c)
816.71(e)(1)	816.74(b)	816.74(b)
816.71(e)(2)	816.74(c)	816.74(c)
816.71(e)(3)	816.102(g) and 816.74(g)	816.74(a) and 816.74(g)
816.71(e)(4)	816.102(h) and 816.74(f)	816.74(a) and 816.74(f)
816.71(e)(5)	816.102(f)	816.74(a)
816.71(f)(1)	816.74(d)(4)	816.74(d)(4)
816.71(f)(2)	816.43	816.74(d)
816.71(f)(3)	816.74(d)	816.74(d)
816.71(g)	816.102(j) and 816.74(e)	816.74(a) and 816.74(e)
816.71(h)	Deleted	816.74(c)
816.71(i)	816.102(e)	816.74(a)
816.74(b)	816.74(c)	816.74(c)
816.74(c)	816.74(c)	816.74(c)
816.74(d)(1)	816.74(d)(1)	816.74(d)(1)
816.74(d)(2)	816.74(d)(2)	816.74(d)(2)
816.74(e)	816.74(h)	816.74(h)
816.102(a)(4)	816.74(d)(3)	816.74(d)(3)

1. Sections 816.74(a) and 817.74(a)

Final § 816.74(a) is being issued as proposed. In it, OSM has substituted references to the backfilling and grading rules in place of the references to the general requirements for the disposal of excess spoil.

Former § 816.74(a) authorized the regulatory authority to approve the disposal of excess spoil on preexisting benches "provided that all the standards set forth in § 816.71(a), (b)(1) [and] (d) through (i) . . . are met." The references to § 816.71 contain the general requirements for the disposal of excess spoil. The final rule substitutes references to § 816.102 (c), (e) through (h), and (j) for the § 816.71 references. Section 816.102 contains the backfilling and grading counterparts to the excess spoil disposal regulations of § 816.71. The substitution has the effect of conforming the requirements for disposal of excess spoil on a preexisting bench with the requirements for backfilling and grading spoil on an actively mined bench.

As proposed, OSM is adding a requirement to final § 816.74(a) that the affected portion of the preexisting bench be permitted. Because § 816.71 (a) requires that the disposal of excess spoil occur "within the permit area," and the substituted references to § 816.102 do not refer to the permit area, final § 816.74(a) has been written to explicitly require that "the affected portion of the preexisting bench is permitted." Thus, the final rule requires, as did the former rule, that the affected portion of the preexisting bench be permitted. This provision allows the affected area to be either within the permit area where the excess spoil was generated, or in a separately permitted area.

Section 816.102(c) requires compaction of material where advisable to ensure the stability of the spoil material and to prevent leaching of toxic materials. The section generally replaces the former requirement in § 816.71(a)(2). OSM is adding to a later paragraph (816.74(c)) the requirement in § 816.71(a)(2) that the spoil be placed in a controlled manner.

The reference to § 816.102(e) requires that the disposal of coal processing waste and underground development waste be in accordance with §§ 816.81 through 816.83, except that a long term static safety factor of 1.3 be achieved. This reference replaces the former reference to § 816.71(i) which provided similar requirements.

Section 816.102(f) protects surface and groundwater from the adverse effects of acid, toxic and combustible materials by requiring that exposed coal seams, acid or toxic forming materials and combustible materials be covered. The new reference replaces the reference to §§ 816.71(a)(1) and 816.71(e)(5) which have similar requirements.

Section 816.102(g) allows cut and fill terraces to be constructed in the backfill if certain conditions are satisfied. This reference replaces the provisions of § 816.71(e)(3) which allowed cut and fill terraces on excess spoil disposal areas. Section 816.71(e)(3) contains a requirement that the outslope of the terrace be limited to a maximum slope of 2h:1v, a requirement not in § 816.102(g). As proposed, OSM is deleting this limitation from cut and fill terraces constructed on preexisting benches. The limit on the outslope, as proposed, will be the angle of repose as detailed in § 816.74(d)(2).

The reference to § 816.102(h) allows small depressions to be constructed on the fill material. Section 816.71(e)(4) provided a similar authorization. The one difference between the two provisions is that § 816.71(e)(4) prohibits the construction of permanent impoundments on excess spoil disposal areas. In the preamble to the proposed rule OSM explained:

> although the rule would not explicitly prohibit permanent impoundments, § 816.74(a) does not reference § 816.102(i) which authorizes permanent impoundments in certain circumstances and the regulatory authority would not be authorized to allow permanent impoundments on preexisting benches. (53 FR 43975, October 31, 1988)

In response to a comment, which is addressed in the discussion of final § 816.74(f), OSM is adding a paragraph, final § 816.74(f), to the rule which prohibits permanent impoundments on preexisting benches.

The final rule references § 816.102(j), the backfilling and grading rule for controlling stabilization and erosion. This replaces the requirement in § 816.71(g) which addresses surface area stabilization, erosion and revegetation. The last sentence of § 816.71(g) which requires that "[a]ll disturbed areas, including diversion channels that are not riprapped or otherwise protected, shall be revegetated upon completion of construction" does not have a counterpart in § 816.102 and has been added as proposed as final § 816.74(e).

2. Sections 816.74(b) and 817.74(b)

Section 816.74(b) is being issued as proposed except for one change. The proposed rule required the removal of "vegetation." The final rule has been changed to require the removal of "vegetation and organic materials." This returns the final rule to the former language in § 816.71(e)(1). The change from the proposal results from a comment which noted that the Act at section 515(b)(22)(B) requires the removal of all "organic matter". OSM agrees that there is a distinction between the terms "organic matter" and "vegetation." The final rule, therefore, requires removal of all vegetation and organic material as required by the former rules and the statute.

Final § 816.74(b) requires the removal of all vegetation and organic material from the affected portion of the preexisting bench prior to the placement of the excess spoil; it cross-references the permanent program topsoil performance standards at 30 CFR 816.22; and it allows the use of topsoil substitutes in accordance with § 816.22(b) where insufficient topsoil is available on the preexisting bench.

Formerly, the cross reference to § 816.71(e)(1) provided for the removal of vegetative and organic materials prior to the placement of excess spoil, the removal, segregation, storage and redistribution of topsoil, and the use of organic material as mulch or as an additive to topsoil. These requirements are not in § 816.102, therefore, they have been added as final § 816.74(b).

3. Sections 816.74(c) and 817.74(c) (Proposed as §§ 816.74 (b) and (c) and 817.74 (b) and (c))

Final § 816.74(c) contains six provisions which state—

- The fill shall be designed and constructed using current, prudent engineering practices.
- The design shall be certified by a registered professional engineer.
- Spoil shall be placed only on the solid portion of the bench.
- Spoil shall be placed in a controlled manner and concurrently compacted as necessary.
- The spoil shall achieve a long term static safety factor of 1.3.
- Spoil deposited on any fill portion of a bench shall be treated as excess spoil under § 816.71.

a. *The fill shall be designed and constructed using current, prudent engineering practices.* Final § 816.74(c)'s first sentence tracks the language of § 816.74(c) with the phrase "and constructed" added. As proposed, the specialized inspection requirements in § 816.71(h) for excess spoil are being replaced by the normal inspection requirements for all permitted areas. OSM is also adding through the new rule a requirement that fills be constructed using current, prudent engineering practices. The additional language is included in response to a comment to the proposed rules which

expressed concern over the deletion of the inspections formerly required by § 816.74(a)'s reference to § 816.71(h).

The environmental hazards posed by disposing of excess spoil on the solid portion of existing level benches are no greater than the hazards posed by backfilling spoil on an active bench. A regulatory authority inspects backfilling of active benches under the requirements in 30 CFR 840.11. These inspections have proven to be an effective means of controlling against the hazards of backfilling on an active bench and of ensuring compliance with the performance standards and with the reclamation plan. OSM believes that these inspections will be an equally effective means of protecting against the hazards posed by disposing of excess spoil on preexisting benches. Therefore, the final rule replaces the inspections described in § 816.71(h) with the normal inspection process described in § 840.11. OSM continues to believe that the additional safeguards provided in § 816.71(h) are appropriate for those excess spoil disposal areas which pose significantly greater risk of environmental harm such as valley fills and head-of-hollow fills.

b. *The design shall be certified by a registered professional engineer.* The second provision of final § 816.74(c) provides for the certification of the design by a registered professional engineer. OSM did not include this requirement in its proposed rule. However, certification is required for all excess spoil disposal areas by section 515(b)(22)(H) of the Act as was pointed out by a commenter to the proposed rule. Certification was formerly required by cross reference to § 816.71(b)(1). In order to retain the statutory requirement while avoiding cross reference to the excess spoil rules, the sentence is being added to this paragraph.

The new rule uses the term "registered professional engineer" instead of the term "qualified registered professional engineer" which appears in § 816.71(b)(1). In 1983 when § 816.71 was published, the preamble explained that OSM had found some practicing registered professional engineers involved in design and certification of excess spoil fills who did not have sufficient experience to certify all phases of design and construction (48 FR 32913, July 19, 1983). OSM continues to believe that the risks posed by certain types of excess spoil disposal areas require specialized knowledge beyond the minimum standards posed by state certification boards. The particular specialized knowledge needed for excess spoil fills relates to the design of the underdrain system to prevent water infiltration from springs or seeps into the fill and the design of rock toe buttress or keyway cuts to insure stability of the fill on a downslope. However, these risks do not exist when excess spoil is disposed on the solid level foundation required to invoke this rule. For this reason, this rule only provides that the design be certified by a registered professional engineer. OSM does not mean to suggest that the registered professional engineer does not have to be qualifed. OSM intends merely that the qualifications necessary to design the disposal of excess spoil on a solid level pre-existing bench may not necessarily be the same as those required for the design and construction of structures covered by § 816.71(b).

c. *Spoil shall be placed only on the solid portion of the bench.* This requirement was proposed as § 816.74(c). It formerly appeared as §816.74(b). Some concern was expressed by commenters that preexisting benches may contain areas composed of filled areas which may not have the stability of true rock floored benches. The rules being issued today only apply to disposal on solid preexisting benches. Although the requirement for foundation examinations in § 816.71(d) has been deleted as proposed, the professional engineer responsible for designing the fill and the regulatory authority approving the permit are still responsible for ensuring that disposal under these rules is limited to solid portions of the bench. In order to invoke the provisions of this section, the professional engineer's design must certify that the disposal area is a solid bench. Therefore, any foundation analysis necessary to establish the qualification of the proposed disposal site under this section must have already been performed and any additional foundation analysis would be redundant.

d. *Spoil shall be placed in a controlled manner and concurrently compacted as necessary.* The proposed rule did not require, as does the statute in section 515(b)(22)(A) and the former rules in § 816.71(e)(2) placement in a controlled manner and concurrent compaction as necessary. OSM has added these provisions in the final rules as required by the Act. The former rules provide for this requirement in § 816.71(e)(2). Additional discussion on spoil placement and compaction is given in response to a comment at 12.b of this rulemaking.

e. *The spoil shall achieve a long-term static safety factor of 1.3.* Excess spoil disposed on preexisting benches must achieve a long-term static safety factor of 1.3. Obtaining a minimum long-term safety factor of 1.3 is a general requirement for all backfilling and grading as specified in § 816.102 and was a requirement for disposal of excess spoil on preexisting benches in prior § 816.74(c).

f. *Spoil deposited on any fill portion of a bench shall be treated as excess spoil under § 816.71.* The final sentence has been added in response to a comment to provide further guidance on situations in which there are both a solid bench and a fill area to be used to dispose of excess spoil. In such cases the solid portion of a preexisting bench is governed by § 816.74 while the fill portion is governed by § 816.71.

4. Sections 816.74(d) and 817.74(d) (Proposed as §§ 816.74(e) and 817.74(e))

Final § 816.74(d) (1) and (2) require that the preexisting bench be backfilled and graded to achieve the most moderate slope possible which does not exceed the angle of repose, and to eliminate the highwall to the maximum extent technically practical. These two paragraphs appear in the former rules and are being issued as proposed.

Final § 816.74(d)(3) requires, as proposed, that the preexisting bench be backfilled and graded to "[m]inimize erosion and water polution both on and off the site." This paragraph picks up the backfilling and grading provision at § 816.102(a)(4), which is not otherwise referenced by the rule. This requirement protects the hydrologic balance.

Proposed § 816.74(d)(4) required that the preexisting bench be backfilled and graded to "[p]revent water infiltration into the backfill from springs, water courses, or seeps, and ensure stability." This corresponded with the requirements of § 816.71(f) which had been referenced by former § 816.74(a). Final § 816.74(d)(4) has been changed to quote the language from § 816.71(f)(1). The language of final § 816.71(d)(4) is closer to the statutory requirement of section 515(b)(22)(D) than the proposed language. The other two requirements formerly referenced by § 816.74, that is, § 816.71(f)(2) and § 816.71(f)(3), are expressly incorporated into the final rule through the provisions of § 816.74(d)(4). Section 816.71(f)(2) provides only a cross reference to § 816.43 which applies in all cases to permitted areas. Section 816.71(f)(3) provides design standards for underdrains when they are needed. The preamble to the final § 816.71(f)(3) clearly states that:

> these specific requirements apply to all underdrain systems whether or not the disposal area falls within the definition of a

head-of-hollow or valley fill. (48 FR 32917, July 19, 1983)

(See the preceding discussion of § 816.74(a).) A comment relevant to issues addressed in this paragraph appears under section 12.d of this rulemaking.

5. Sections 816.74(e) and 817.74(e) (Proposed as §§ 816.74(f) and 817.74(f))

Final § 816.74(e) is being issued as proposed with the exception that its section number has been changed as noted above. It requires that

[a]ll disturbed areas, including diversion channels that are not riprapped or otherwise protected, shall be revegetated upon completion of construction.

This adds as an express provision to § 816.74 the last sentence of § 816.71(g), which was formerly referenced in § 816.74(a). (See preceding discussion of § 816.74(a).)

6. Former Sections 816.74(e) and 817.74(e)

Former § 816.74(e) is redesignated as final § 816.74(h). The proposed rule redesignated § 816.74(e) as § 816.74(g).

7. Sections 816.74(f) and 817.74(f)

Final § 816.74(f) prohibits the construction of permanent impoundments on preexisting benches backfilled with excess spoil. As stated in the preamble to the proposed rule and as mentioned earlier in the discussion of § 816.74(a), it is OSM's policy to prohibit the construction of permanent impoundments on preexisting benches backfilled with excess spoil. However, the proposed rule did not explicitly prohibit impoundments constructed on excess spoil as the former rules did. In response to the suggestion of a commenter, OSM is explicitly stating that policy by adding such a prohibition as § 816.74(f).

8. Sections 816.74(g) and 817.74(g)

Final § 816.74(g) requires that the

[f]inal configuration of the backfill must be compatible with the natural drainage patterns and the surrounding area and support the approved postmining land use.

This section is issued in response to a comment received and comports with the requirements of section 515(b)(22)(G) of the Act. Similar requirements were specified at formerly referenced §§ 816.71(e) (2) and (3), and replicate others found at § 816.102(a)(5) but not cross-referenced. OSM agrees that the provision is needed for completeness and has included it with the final rules.

9. Sections 816.74(h) and 817.74(h) (Proposed as § 816.74(g) and § 817.74(g))

Former § 816.74(e) is redesignated as final § 816.74(i).

10. Conforming Changes to Parts 780 and 784

After review of the proposed rules, OSM determined that additional conforming changes are required. OSM is making three changes to these permitting rules to accommodate the changes proposed and made to the performance standards at final § 816.74.

a. *Section 780.14(c).* OSM is inserting "816.74(c)" into the list of cross referenced sections which are excepted from this rule allowing qualified registered professional engineers, professional land geologists or land surveyors to prepare and certify cross sections, maps and plans. Included among these exceptions is a reference to § 816.71(b) which, after today's rule, no longer applies to the disposal of excess spoil on preexisting benches. The effect of the insertion of § 816.74(c) into § 780.14(c) would be to continue the previous exception afforded by the reference to § 816.71(b). The insertion of § 816.74(c) would require that the cross sections, maps and plans prescribed by § 780.14(c) for the disposal of excess spoil on preexisting benches be certified by a registered professional engineer. This would make consistent the permitting and performance standards certification requirements for such disposal on preexisting benches.

b. *Section 780.35.* Section 780.35 governs the disposal of excess spoil. OSM is adding a phrase to the start of paragraph (b) which will read "[e]xcept for the disposal of excess spoil on preexisting benches,". The change conforms the permitting requirements for disposal of excess spoil on preexisting benches at § 780.35 to the changes made to the performance standards for disposal of excess spoil on preexisting benches at § 816.74. The deletion from § 816.74 of the foundation analysis formerly required by its reference to § 780.71(d), as discussed earlier, obviates the need for a permit application to submit the results of a geotechnical investigation.

Preexisting bench areas used for the disposal of excess spoil are, of course, still subject to all the other permit application requirements that apply to surface coal mining operations including the requirement of § 780.35(a) to submit a description (with maps and drawings) of the disposal area. As discussed earlier, the use of § 816.74 to govern an excess spoil disposal site is limited to those areas which are established as solid, rock floored benches by the design certified by the registered professional engineer.

c. *Section 784.23(c).* OSM is inserting "817.84(c)" into the list of cross referenced sections which are excepted from this rule allowing qualified registered professional engineers, professional land geologists or land surveyors to prepare and certify sections, maps and plans. Included among these exceptions is a reference to § 817.71(b) which, after today's rule, no longer applies to the disposal of excess spoil on preexisting benches. The effect of the insertion of § 817.74(c) and § 784.23(c) would be to continue the previous exception afforded by the reference to 817.71(b). The insertion of § 717.74(c) would require that the cross sections, maps and plans prescribed by § 784.23(c) for the disposal of excess spoil on preexisting benches be certified by a registered professional engineer. This would make consistent the permitting and performance standards certification requirements for such disposal on preexisting benches.

11. Other Comments

A commenter, supportive of the proposed rule, noted that the proposed revisions remove a significant impediment to reclaiming previously mined areas. The commenter also recommended OSM not apply the rule in a manner that would discourage voluntary reclamation by industry through no-cost AML contracts with the State Regulatory Authorities (SRA).

The requirements in this final rule for the disposal of excess spoil material on preexisting benches are designed to parallel the backfilling and grading rules and to provide an incentive for industry to reclaim preexisting areas which otherwise may not be reclaimed through remining. OSM has no intention to apply this rulemaking in a manner that would discourage voluntary reclamation by industry. Any disposal of excess spoil from active mining operations must be performed in accordance with the requirements of this rule and any other applicable requirements of the regulatory program and the Act. The use of no-cost contracts under the Abandoned Mine Lands Program however is not germane to this rulemaking since projects supervised under that program are not subject to jurisdiction under title V.

Several commenters expressed concern about the placement of excess spoil on preexisting benches many preexisting benches are, in part, fill benches resulting from the pushing of material over the outslope. Since fill

benches often lack the stability to support further placement of spoil material, the commenters fear that excess spoil will be placed on the fill portion of the preexisting benches, not just on the rock bench, and will create the potential for mass movement.

Other commenters indicated they believed, in general, that the proposed rules adequately address foundation preparation and placement requirements. Nevertheless, these commenters also emphasized that care should be taken to insure that excess spoil material be placed only on the solid portion of the bench.

OSM recognizes that there are areas where there is material on the downslope from previous mining operations. There are also areas where material from previous operations remains on the bench. Therefore, OSM expressly states in final §§ 816.74(c) and 817.74(c) that this section of the rules only applies when excess spoil is placed on the solid portion of a bench and that § 816.17 applies when excess spoil is placed on a fill portion. OSM has included in the final rule a requirement that the design must be certified by a registered professional engineer. This is a requirement of the former rules but was not included in the proposed rule. OSM is retaining the professional engineer certification because of the need to establish that the foundation of the preexisting bench is a solid foundation.

A commenter stated that the proposed rule would encourage preexisting highwall reclamation wihtout sacrificing environmental quality. However, the commenter recommended inclusion of the contemporaneous requirements of 30 CFR 816/817.100 as well as the time and distance limitations of proposed § 816.101.

OSM agrees the proposed language will encourage the reclamation of preexisting highwalls. While the general principles of contemporaneous reclamation in § 816.100 apply to all surface coal mining operations, the specific schedules in 816.101 for area and contour mines do not apply to disposal of excess spoil on preexisting benches.

Commenters also raised a related issue of seepage and its adverse affect on stability of the backfilled areas and, therefore, strongly recommended OSM create a separate provision for disposal of excess spoil on preexisting benches incorporating the ten (10) requirements described and discussed below.

a. *The disposal area must be permitted and bonded.* OSM agrees. Proposed and final § 816.74(a) require the disposal areas to be permitted. Section 30 CFR 800.11(a) requires that all areas of the permit be covered by a bond prior to issuing the permit.

b. *The spoil must be transported and placed in a controlled manner, compacted concurrently and in such a way as to assure mass stability and to prevent mass movement, as required by section 515(b)(22) of the Act.* Section 515(b)(22)(A) specifies that

> spoil [be] transported and placed * * * in position for concurrent compaction and in such a way as to assure mass stability * * *.

OSM agrees it is necessary to require spoil to be placed in a controlled manner and, if necessary for stability, compacted concurrently. The language of the Act does not, however, require concurrent compaction as the commenter alleges. Section 515(b)(22) specifies that

> spoil [be] transported and *placed * * * in position for concurrent compaction* and in such a way as to assure mass stability. (emphasis added).

The emphasized language does not specifically require concurrent compaction. It only requires that the spoil be placed in position for concurrent compaction. The manifest concern of this statutory provision is that mass stability be assured. Final § 816.74(c) addresses that concern by providing that the spoil be placed in a controlled manner and compacted concurrently as necessary to attain the required stability. It may further be noted that the general requirements for disposal of excess spoil at § 816.71 have contained a similar provision since their promulgation in 1979. (44 FR 15311, March 13, 1979). Final § 816.74 (c) also provides that the fill shall be designed and constructed, using current, prudent engineering practices to attain a long-term static safety factor of 1.3 for all portions of the fill. Finally, the design must be certified by a registered professional engineer.

OSM also agrees that spoil must be transported and placed on preexisting benches "in such a way as to assure mass stability and to prevent mass movement." This means that under this section of the rules spoil may be placed only over rock floored portions of benches and not over fill areas which extend over the outslope. It also means that preexisting bench surfaces must be prepared prior to placement of the excess spoil. Preparation includes drainage of any existing impoundments and the removal of organic materials and vegetation. The regulatory authority has both the responsibility and the authority to require these actions under §§ 816 and 817.74 of the final rule and the §§ 816 and 817.102(c), (f) through (h), and (j) requirements cross-referenced therein.

c. *All organic material must be removed prior to spoil placement as mandated by section 515(b)(22) of the Act.* OSM agree. The requirement in §§ 816.74(b) and 817.74(b) of the final rule has been amended to add the term organic material to the term vegetation. Prior rules have used the terminology "vegetation and organic material" which is being retained in the final rule.

d. *The disposal area must not contain springs, wet weather seeps, natural water courses or their lateral water discharges (i.e., from auger or old underground mine workings) unless section 515(b)(22)(D) of the Act is complied with.* OSM agrees. The prevention of adverse effects from seepage on a backfill's stability is addressed in §§ 816.74(d)(4) and 817.74(d)(4) of the final rule. The final rule was changed from the proposed language to quote the requirement imposed by the former reference to § 816.71(f)(1). Therefore there is no change to this existing requirement under the new rule.

e. *The design of the spoil disposal area on the preexisting bench must be certified by a qualified registered professional engineer in conformance with professional standards, as mandated by section 515(b)(22)(H) of the Act, and not merely those fills using coal mine waste as proposed.* OSM agrees. Final 816.74(c) provides that backfills must have their design certified by a registered professional engineer. Certification is a statutory requirement in section 515(3)(22)(H) of the Act which, while not in the proposed rule, is included in the final.

f. *Standards for foundation and bench stability analyses for the proposed disposal area must be tailored to the nature of the proposed disposal areas.* OSM agrees that preexisting bench disposal areas may differ depending on age and the mining methods employed during the past mining operation and may require different preparation prior to placing the spoil in the backfill. OSM remains satisfied that the performance standard in § 816.74(c) for the use of prudent engineering practices during design and construction, coupled with a requirement to achieve a long term static factor of safety of 1.3 and limiting the rule to cover only disposal on the solid portion of the bench will provide the necessary regulatory controls to ensure stability. Nevertheless, the regulatory authorities may tailor additional program requirements to their individual needs. Further, nothing will prohibit the regulatory authority from

conditioning permits with more stringent criteria based on site specific conditions.

g. *There must be an explicit prohibition on the creation of permanent impoundments on preexisting benches.* OSM agrees. Accordingly, proposed §§ 816.74 and 817.74 were revised by adding a new paragraph (f). The final rule expressly prohibits permanent impoundments on the backfill areas of preexisting benches. For further information see II. D. 8., addressing §§ 816.74(f) and 817.74(f), of this final rulemaking.

h. *There must be a requirement that the final configuration of the backfill be compatible with the natural drainage pattern and surroundings and be suitable for its intended uses.* OMS agrees. Since a similar requirement does not exist in §§ 816.102 and 817.102, OSM has added this requirement as §§ 816.74(g) and 817.74(g) of the final rule. As discussed earlier (II. D. 9. addressing §§ 816.74(g) and 817.74(g) of this final rulemaking) paragraph (g) of §§ 816.74 and 817.74 requires the final configuration of the backfill be compatible with the natural drainage patterns of the surrounding area and support the approved post mining land use.

i. *There must be compliance with all other requirements of section 515(b)(22) of the Act.* OSM agrees that compliance with the applicable requirements of section 515(b)(22) of the Act is necessary. Table 2 is a cross reference between the subsection of the Act and the former and new regulatory requirement.

TABLE 2.—CROSS REFERENCE THE ACT VERSUS FORMER AND NEW IMPLEMENTING RULES FOR EXCESS SPOIL DISPOSAL

The Act provision	Former rule	New rule
515(b)(22)(A)	30 CFR 816.71 (a)(2), (e)(2)	30 CFR 816.74(c) and 816.102(c)
515(b)(22)(B)	816.71 (a), (e)(1)	816.74 (a), (b)
515(b)(22)(C)	816.71(f)(1)	816.74(d)(4)
515(b)(22)(D)	816.71(f)(1)	816.74(d)(4)
515(b)(22)(E)*	Not applicable*	Not applicable*
515(b)(22)(F)*	Not applicable*	Not applicable*
515(b)(22)(G)	816.71(e) (2) and (3)	816.74(g)
515(b)(22)(H)	816.71(b)(1)	816.74(c)
515(b)(22)(I)	816.71(a)	816.74(a)

*The Act sections 515(b)(22) (E) and (F) apply to slopes, OSM rules for disposal of excess spoil on preexisting benches only apply to solid portions of existing level benches.

j. *There must be a requirement for inspection of the spoil disposal area prior to placement of spoil to ensure that factors which potentially could lead to the creation of an unstable fill are considered and properly treated.* OSM agrees that factors which could lead to the creation of an unstable fill must be considered prior to approving a permit for the site. Inspection of the spoil disposal area prior to placement of spoil to ensure that such factors are properly treated is a reasonable measure. Final § 816.74(c) requires that

> the fill shall be designed and constructed using current, prudent engineering practices * * * be certified by a registered professional engineer * * * and the spoil be placed * * * to attain a long term static safety factor of 1.3 for all portions of the fill.

These provisions ensure that the design and construction of spoil fills includes the proper treatment of factors which potentially could lead to the creation of an unstable fill.

E. Sections 816.81, 817.81 and 816.89, 817.89 Coal Mine Waste: General Requirements

1. Section 816.81(a)

OSM is amending § 816.81(a) in response to the district court decision concerning end or side dumping of coal mine waste In re Permanent II (Round III), 620 F. Supp. at 1534–38. As proposed, the final rule now requires that coal mine waste be "hauled or conveyed" instead of the former language which only required coal mine waste to be "placed." The final rule adds two additional phrases to the proposed rule. Both changes have been made in response to comments and will be discussed more fully later. First, the phrase, "disposed of in an area other than the mine workings or excavations" has been added to the first sentence of § 816.81(a). Second, the phrase, "with final placement in a controlled manner" has been added to the second sentence of § 816.81(a).

OSM believes the final placement of coal mine waste by end or side dumping is inherently dangerous. As discussed in the preamble to the 1979 rule (44 FR 15209, March 13, 1983), the lack of control over compaction when material is end or side dumped may lead to instability and permeability. Instability or permeability may in turn lead to combustion, erosion, and oxidation of pyrite resulting in water quality degradation. As will be discussed later in greater detail, OSM will allow controlled gravity transport of coal waste when its final placement is accompanied by such additional steps as may be required to meet the performance standards of § 816.81.

OSM maintains, as it did in the preamble to the 1983 rule (48 FR 44011, September 26, 1983), that the controlled gravity transport of coal mine waste is consistent with the Act. The legislative history of the Act does not indicate that the Congress intended OSM to regulate the transportation of coal mine waste to the disposal site.

The practice of transporting coal mine waste to a disposal area through methods other than direct hauling is well documented in the technical literature. (See, for example, Engineering and Design Manual—Coal Refuse Disposal Facilities, pp. 8.22–8.75, by E. D'Appolonia Consulting Engineers for the Mine Safety and Health Administration.) Accepted methods include conveyor belts and tramways, useful in mountainous terrain where haul road construction is difficult or where steep grades decrease the efficiency of individual hauling units. (See id. at p. 8.45; and Pit Slope Manual, "Chapter 9: Waste Embankments," p. 96, by the Canada Center for Mineral and Energy Technology.)

One commenter supported the language in § 816.81(a) of the proposed rule which requires that coal mine waste must be hauled and conveyed and placed in a controlled manner. The commenter stated that the possibility of spontaneous combustion from improper compaction, increased potential for saturation and (stability) failure, and the difficulty of effectively and evenly compacting end dumped material, described in the 1979 preamble, continue

to be valid reasons to reject end and side dumping of coal and to require controlled placement after hauling or conveying the waste.

On January 29, 1988, the D.C. Court of Appeals considered the threats of fill instability and spontaneous combustion. *NWF* v. *Hodel*, 839 F.2d 694, 731. The court upheld the 1983 revisions to 30 CFR 816.81 and 816.83 which eliminated the specific absolute design criteria prescribing compaction density, lift thickness and other "how to" rules on the basis of existing performance standards prescribing minimum satisfactory end results. The specific performance standards cited by the court as reasonably promoting fill stability and incombustability were the requirements that the coal mine waste be placed in a controlled manner to prevent combustion and that the disposal facility be designed to obtain a minimum long-term static safety factor of 1.5. 30 CFR 816.81(a)(5) and (c)(2). These performance standards continue in the current regulations.

The provisions of final § 816.81(a)(1) that require coal mine waste to be "hauled or conveyed and placed for final placement in a controlled manner * * *" preclude end and side dumping as a means of final placement of coal waste. As will be subsequently discussed in response to other comments, additional steps following the transportation of coal waste to a storage facility would invariably be required to achieve the performance standards specified in § 816.81.

Four commenters objected to what they described as OSM's intention to regulate the transportation of coal waste by preventing the disposal of coal waste using end or side dumping. Those commenters asserted that Congress did not intend OSM to regulate the transport of coal waste and that the court did not ask OSM to prohibit end or side dumping, but only required OSM to explain why this practice is reasonable. One of these commenters also contended that OSM was reversing its position by preventing controlled gravity transport in the proposed rule. The commenter strongly recommended that OSM reevaluate the proposed rule and repropose it with adequate rationale in the preamble to support the rulemaking.

OSM believes that these commenters, in the main, have misunderstood the meaning of the terms "hauled or conveyed" as applied to this rule. "Hauled or conveyed" includes virtually all forms of transporting coal waste including trucks and systems such as conveyor belts and tramways. OSM is not prohibiting any form of transportation of coal waste but rather is regulating its final placement. OSM rules have sought to protect against the problems associated with coal mine waste which occur in its placement rather than its transportation. OSM is not changing that policy.

One commenter who objected to the proposed change asked whether additional steps taken by the operators following end or side dumping would be acceptable to OSM. The commenter stated that it is unclear from the preamble of the proposed rule whether end or side dumping is prohibited as a method of placement prior to spreading (i.e., transportation) or only as a method of final placement. The commenter suggested that, if end or side dumping is prohibited as a method of final placement and not transportation, OSM insert the phrase "with final placement in a controlled manner" after the terms "hauled or conveyed". This commenter also submitted that the use of conveyor belts and tramways should be considered acceptable methods of controlled placement of coal waste under any final rule.

In response to the commenter's suggestion, the words: "for final placement" have been inserted between the word "placed" and "in a controlled manner" in the final rule. OSM has made the addition to emphasize that the regulatory controls of activities which place the coal mine waste for disposal are distinguished from the regulatory controls for activities which transport coal mine waste to a storage facility. OSM is unaware of any means of transporting coal mine waste to a storage facility which would achieve the performance standards required by § 816.81 for disposal without some additional steps being taken. These steps, however, may vary depending on the design of the disposal area, the individual site conditions, and the characteristics of the waste. However, the performance standards in § 816.81 cannot be achieved by gravity alone, as would be the case if end or side dumping were the means of final placement. Therefore, while there may be a variety of acceptable ways of transporting the coal mine waste to the disposal area, the final placement of the coal mine waste must be controlled so that the disposal achieves all the performance standards in § 816.81. Thus, final § 816.81 will read

[c]oal mine waste shall be hauled or conveyed and placed for final placement in a controlled manner to * * *.

One commenter stated that the rule does not apply to the material disposed in the mine workings or excavations as indicated in sections 515(b)(11) and 516(b)(4) of the Act. The commenter maintained that the rule applies only to the surface disposal of coal mine waste in areas other than the mine workings and excavations and recommended that appropriate rule language be added to this section to make that clear.

The commenter is correct. OSM does not intend for this rule to apply to material disposed in the mine workings or excavations. The language in proposed § 816.81(a) has been changed by adding the phrase "disposed of in areas other than the mine working or excavation." The new text is taken from the statutory limitation on the application of these rules contained in sections 515(b)(11) and 516(b)(4) of the Act.

2. Sections 816.89(d) and 817.89(d) EPA Regulations on Hazardous Waste

As proposed, OSM is deleting paragraph (d) from §§ 816.89 and 817.89. As stated in the Background section, these paragraphs were added to the regulations in 1983 and suspended in 1986 when the district court ruled that OSM had failed to follow the notice and comment provisions of the Administrative Procedures Act. The paragraphs required that any noncoal mine waste defined as "hazardous" under section 3001 of the Resource Conservation and Recovery Act (RCRA) must be handled in accordance with subtitle C and any implementing regulations of that Act.

OSM received two comments on the deletion. A commenter opposed the deletion on the basis that OSM was obligated to coordinate the implementation of the Act with other Federal laws, including RCRA, and must continue to require compliance by permit applicants with the applicable waste laws. Another commenter supported the deletion stating that the Act operates in concert with, but not in place of, other environmental laws and regulations.

Section 816.89(d) was originally issued at the request of EPA. In reassessing § 816.89(d) for the purpose of this rulemaking, OSM has decided to delete the paragraph for the following reasons. The incorporation by reference of certain RCRA provisions in § 816.89(d) would have required OSM and State regulatory authorities to assume permitting, inspection and enforcement responsibilities over those RCRA provisions which are assigned by Congress to EPA. Assuming those responsibilities is not required by the Act nor is it a task for which the Congress appropriates funds to OSM or the State regulatory authorities.

Enforcing RCRA provisions requires regulatory units structured and staffed appropriate to the task, a task significantly different from regulating the environmental impacts of coal mining *per se*.

An operator's duties under RCRA regarding disposal of hazardous noncoal waste will continue to be regulated by EPA. OSM, for its part, will continue, consistent with its jurisdiction under the Act, to coordinate its regulatory program with EPA to facilitate the implementation of RCRA regulations.

F. Section 816.100 Contemporaneous Reclamation

As proposed, the final sentence in § 816.100 has been deleted. This change conforms § 816.100 to the addition of § 816.101. The sentence being deleted authorized the regulatory authority to establish schedules for defining contemporaneous reclamation. This authorization is being replaced with the guidance contained in § 816.101.

G. Section 816.101 Backfilling and Grading: Time and Distance Requirements

On October 31, 1988, OSM proposed § 816.101 which contained four paragraphs. Section 816.101(a) contained time and distance schedules for contour and area mines as well as provisions for the regulatory authority to establish schedules for other mining methods. Section 816.101(b) allowed the regulatory authority to submit alternative schedules in lieu of those in section (a). Section 816.101(c) defined the parameters under which alternative schedules submitted under section (b) would be evaluated. Section 816.101(d) allowed the regulatory authority to extend the backfilling and grading time limit for a portion of the permit area if the permittee demonstrated through the permit application that additional time was necessary.

On April 17, 1990, OSM published a Notice of Inquiry in the **Federal Register** to provide an opportunity for public comment on whether additional regulations were needed to control the contemporaneous reclamation of multiple seam and mountaintop removal mining operations (55 FR 14319, April 17, 1990). OSM published the Notice of Inquiry because of comments received on this proposed rule and reports of problems in enforcing contemporaneous reclamation at multiple seam and mountaintop sites. A further discussion of this notice of inquiry appears in section G. 5., Notice of Inquiry on Multiple Seam Mining and Mountaintop Removal Operations, of this preamble.

The final rule contains two paragraphs. As proposed, final § 816.101(a) provides the time and distance schedules for area and contour mines and requires regulatory authorities to establish schedules for other mining methods permitted in their State. Final § 816.101(b) authorizes the regulatory authority to approve extensions to time for rough backfilling and grading for a permit area or a portion of a permit areas, similar to proposed § 816.101(d). OSM is withdrawing proposed § 816.101(b) which would have allowed a regulatory authority to submit schedules in lieu of those in § 816.101(a). Proposed § 816.101(c) detailing the criteria to evaluate alternative schedules has likewise been withdrawn. As will be discussed later, OSM believes the language of the final rule, which is very similar to the rule issued in 1979, provides sufficient guidance to States, while allowing sufficient flexibility to deal with any State- or site-specific problem.

1. Section 816.101(a) Time and Distance Schedules

Final § 816.101(a) contains time and distance schedules for contour and area mining and requires the regulatory authority to establish schedules for other methods of surface mining. For contour mining, § 816.101(a)(1) requires the completion of backfilling and grading within 60 days or 1,500 linear feet following coal removal. For area mining, § 816.101(a)(2) requires completion within 180 days following coal removal, and not more than four spoil ridges behind the pit being worked, the spoil from the active pit constituting the first ridge. Sections 816.101(a) (1) and (2) are identical to the proposed rule. Under § 816.101(a)(3), backfilling and grading schedules for other mining methods shall be established by the regulatory authority. Any schedule established by the regulatory authority must incorporate an inspectable standard between coal removal and the completion of backfilling and grading.

One commenter wanted OSM to clarify that an operation completing the "rough" backfilling and grading stage, but not the final grading stage, would be considered to be in compliance with the time and distance requirements. The commenter also mentioned that final grading must at times be combined with topsoil placement and seeding in order to minimize erosion. Because the 1979 Federal rules recognized this distinction (44 FR 15411, March 13, 1979), the commenter requested OSM clarify the issue in this final rule.

OSM intends backfilling and grading to mean that all of the spoil material has been placed in the mined-out area and the backfilled material is ready for final-grading as specified in § 816.102(j). Thus, backfilling and grading does not include final grading, placing topsoil, and seeding. The 1979 preamble and rules used the phrase "rough backfilling and grading" but did not explain the meaning of the term "rough". Since it was not explained in 1979, OSM chose not to include this wording in the proposed rule. In response to the commenter's request for clarification, OSM has adopted language similar to the 1979 rules; therefore, final § 816.101 reads * * * rough backfilling and grading for surface mining * * *."

A commenter stated that time standards should be eliminated since the distance limitations were felt to be sufficient to ensure contemporaneous reclamation. The commenter believes that the elimination of time standards would eliminate difficulties in inspection related to tracking the number of days between coal removal and backfilling and grading.

OSM disagrees with the comment. The establishment of distance limits without concomitant time limits would not sufficiently ensure that contemporaneous reclamation would occur. For instance, an operator could cease coal extraction prior to proceeding four spoil ridges or 1,500 linear feet. In circumstances such as these, where a distance limit would not apply, a time limit would ensure that reclamation would proceed properly. Alleged enforcement difficulties do not constitute sufficient reason for OSM to retreat from this important performance standard. Moreover, required monthly inspections make it unlikely that the time limits will be abused to any great degree.

The commenter also stated that the term "coal removal" also needs to be defined, so that whatever time standard is applied, it is applied at a clearly defined point. The commenter stated that it is not clear if the time period starts when coal is removed from a point or if it starts when coal removal is completed for a cut or pit.

In a similar vein, several commenters asked OSM to clarify the phrase "following coal removal" for area mining so as to assure that reclamation follows disturbance of the land surface in a timely manner. Citing Save Our Cumberland Mountains, Inc. (Rith Energy), 108 IBLA 70 (1989), these commenters objected to OSM's explanation in that case that the 180-day deadline for backfilling and grading did

not start until after all minable coal was removed from the mine cut. The commenters claimed the OSM's interpretation of "following coal removal" to mean following final removal of all coal from a pit, rather than from any point in the cut or pit, is in contradiction with the Secretary's 1979 interpretation and Congressional intent. Therefore, the commenters contended that reclamation of an area must follow within 180 days of the disturbance of land and coal removal at any point of land within the mine cut, rather than following removal of all coal within the mine cut or pit. On the other hand, another commenter suggested applying the 180 day limit only after final coal removal to ensure that the last pit or cut is reclaimed in a timely fashion.

The time and distance schedules for area and contour mining begin following the completion of coal removal. The phrase "following coal removal" means that no minable coal is left in a particular area of the mine. In the Rith Energy case, referred to by the commenter, the board held that backfilling and grading attaches to an area of land at the time of coal removal, and not at the time of final coal removal from a mining cut. *Id.* 108 IBLA at 80. Therefore, the key to enforcing time and distance schedules is to focus on the area of land rather than coal removal. Practical application of this concept requires that time and distance schedules be calculated from a moving "point", i.e., a small area, of a coal seam from which coal is being removed. In the case of multiple seam mining, the moving "point" would be established as coal is extracted from the lowest coal seam.

A commenter claimed that there is no justification given for the numerical time standards in §§ 816.101(a)(1) and (a)(2) (60 and 180 days, respectively, for contour and area mining). The commenter noted that contemporaneous reclamation is so dependent upon site-specific conditions (e.g., type of mining, equipment, geology, climate, speed of mining), that it cannot be tied to such specific time constraints as OSM proposed. Therefore, the commenter wanted OSM to outline steps for determining contemporaneous reclamation for each operation on a site-by-site basis. In the commenter's view the permit is the place to specify time standards because site and operating conditions are too variable for generic Federal or State rules to be appropriate.

Similarly, another commenter objected to the reimposition of nationwide time and distance requirements for completion of backfilling and grading operations at surface coal mining operations. The commenter stated that OSM deleted identical 1979 regulations in 1983 on the premise that the variety of local conditions in mining States precluded the imposition of national standards, and because the Act does not mandate uniform, nationwide time and distance requirements. The commenter pointed out that the legislative history of the Act fails to mention the necessity for nationwide time and distance requirements to define contemporaneous reclamation. The commenter asserted that it is apparent from the 1988 appeals court decision in *NWF* v. *Hodel,* 839 F.2d 694, (D.C. Cir. 1988) that the Act does not require a national time and distance standard. Therefore, OSM was asked to remove what the commenter described as the arbitrary reference to the nationwide standards, which bear no resemblance to on-the-ground conditions or to OSM's prior position.

The same commenter argued that OSM failed to provide adequate justification in the proposed rule for the reversal in agency position. The commenter insisted that OSM's reliance upon the States' requests for guidance on time and distance schedules and various State programs' adoption of the 1979, or more stringent standards, does not constitute sufficient justification for the rule change. The commenter claimed OSM's reliance upon such State action was flawed because (1) the States had to adopt the 1979 rules to keep their programs consistent with the rules of the Secretary and (2) the States have not wanted to change their rules while the issue remained in the courts and unsettled.

The commenter recommended OSM adopt rules which would allow States to set their own requirements for contemporaneous reclamation based on local conditions and would contain flexible standards to accommodate the distinct circumstances of individual surface coal mining operations.

In establishing a regulatory framework for implementing the Congressional prescriptions for contemporaneous reclamation at section 515(b)(16) OSM has, in the past, adopted two alternatives. In 1979, the regulations provided a nationwide limit on time and distance for contour and area mines and allowed for time limit extensions for specific permit areas in accordance with § 780.18(b)(3). In 1983, OSM removed the time and distance limitations from the national program and provided regulatory authorities with the responsibility for determining schedules for their individual States. The legal challenge to this second alternative resulted in the district court's remand of the regulations for failure to provide States with sufficient guidance in defining contemporaneous reclamation beyond that which was provided in the Act. In Re Permanent Surface Mining Regulation Litigation (II), No. 79–1144 (D.D.C. Oct. 1, 1984).

In affirming the remand with regard to contemporaneous reclamation, the circuit court held that, while the Act does not automatically and inevitably require the Secretary to "flesh out" the contemporaneous reclamation prescriptions of section 515(b)(3) and (b)(16), he did not adequately explain why guidance beyond the statutory requirements sensibly could not be given to local regulators. *NWF* v. *Hodel,* 839 F.2d 694, (D.C. Cir. 1988).

This final rule has a sufficient basis and purpose to be valid. The commenter who asserted that the Secretary failed to justify his reversal from his 1983 rules misconstrues the posture of the issue. The position taken in the 1979 rules on time and distance limits is the only one to which the current rule may properly be weighed against. The Secretary is not now required to justify a reversal from a 1983 policy which the court invalidated. OSM has always intended that there will be an inspectable contemporaneous reclamation standard which will apply to every mining site. In final § 816.101(a) OSM has reestablished national standards for area and contour mines (§ 816.101(a) (1) and (2)) and required the States to set State standards for other types of mining (§ 816.101(a)(3)).

Final § 816.101 is modeled on the 1979 rules. The time and distance schedules for contour and area mining in final § 816.101(a) are identical to those in the 1979 rule. The preamble to that rule (44 FR 15226, March 13, 1979), explained how these schedules were developed. Among other things, OSM stated that "(i)t is necessary to establish a maximum time limit for backfilling and grading to ensure that toxic-forming material in the spoil will not remain exposed to surface runoff over an indefinite period of time. 44 FR 15226 (1979). In light of the substantial additional experience gained with these rules at the State and Federal level since 1983, OSM has reconsidered their utility for providing workable national time and distance standards for which reasonable accommodations can be made for local differences. In this light, OSM has affirmed its earlier conclusions and modeled final § 816.101(a)(1) and (2) after the 1979 rules.

Despite the commenter's assertions of the States' motivation for retaining the 1979 schedules, States, when given the option of removing them from their rules in 1983, did not do so. OSM believes the State rules were not changed because the 1979 provisions are viable and workable for a great majority of contour and area mines. These provisions and schedules simplify mine planning, bonding and inspecting and provide a uniform playing field across State lines for operations which are substantially similar in scope. Permit applicants have found retention of State program provisions governing time and distance schedules as an aid to complying with the permit information requirements of § 780.18. Many permits cite the program time and distance schedule as a means of demonstrating their adherence to backfilling and grading reclamation timetable requirements. In short, where appropriate, nationwide standards have substantial administrative benefits for all concerned.

To the degree that flexibility is required, the final rule in § 816.101(b) provides for such flexibility based upon specific showings by a permittee. This allows for site-specific conditions to be taken into account. For types of mining other than area and contour operations, the State is required to establish State standards in accordance with § 816.101(a)(3). OSM has not defined national standards for mining operations other than area and contour mines. Limits for the remaining types of mining operations, if and where they are conducted, are to be determined on a state-by-state basis. OSM believes that contemporaneous reclamation standards for these operations are best defined by the State regulatory authority.

One commenter complained that, although area mining can be conducted either as a truck and shovel or as a dragline operation, the standard for contemporaneous reclamation of area mines in § 816.101(a)(2) is suitable only for dragline operations. The commenter did not explain the basis for this opinion. OSM disagrees with this comment. In the case of area mining that uses truck and shovel operations, the four spoil ridge criteria would not apply but the time schedule would be appropriate to ensure contemporaneous reclamation.

On a similar tack, another commenter claimed the time and distance requirements for area mining are not adequate in all cases. This commenter wanted the rules to clarify that the 180-day period would not include periods when the operation is temporarily shut down through circumstances beyond the control of the operator (e.g., as a result of labor disputes, weather, etc.).

The provisions of 30 CFR 816.131 on temporary cessation are to be used for temporary shutdown. Anytime an operation is in temporary cessation for 30 days or more because of circumstances such as adverse weather or labor problems or similar reasons the person conducting the surface mining activity is required to notify the regulatory authority. Since the 30 day provision of § 816.131 is within either the 60 or 180 day provisions of § 816.101, there should be no conflict with this provision and the contemporaneous reclamation time limits.

Another commenter questioned the use of "or" instead of "and" in § 816.101(a)(1). The commenter wondered if OSM really intended the time and distance requirements for backfilling and grading in contour mines to be alternatives (i.e., within 60 days or 1500 linear feet). Instead, the commenter suggested that "and" would be more suitable since its use would parallel its use in § 816.101(a)(2) for area mines where backfilling and grading are to be completed with both a specified time and a specified distance.

There is no reason to change the conjunction of § 816.101(a)(1) from "or" to "and". OSM believes that the meaning of this provision is clear that backfilling and grading must be completed within either 60 days or 1500 linear feet following coal removal, whichever comes first.

To have interpreted § 816.101(a)(1) otherwise would have opened its provisions to grave abuse. As previously noted, an operation could have ceased mining short of 1500 linear feet and never have been required to backfill and grade the disturbed area. Such a scenario would conflict with the intent of the Act to compel reclamation as "contemporaneously as practicable" (section 515(b)(16)), "and * * * as possible." (Sec. 102(e)).

2. Section 816.101(a)(3) Schedules for Other Mining Methods

Final § 816.101(a)(3) requires the regulatory authority to establish backfilling and grading schedules for other surface mining methods. This section requires a schedule if mining other than contour or area mining is being conducted within the State. Section 816.101(a)(3) has been revised from the proposed rule to clarify that schedules for mining methods other than contour or area mines also apply where OSM is the regulatory authority.

OSM interprets these provisions as requiring the regulatory authority establish schedules that are inspectable standards.

Because of the diversity which exists in types of operations and areas where such operations are conducted, it is infeasible to suggest that OSM establish national schedules for all methods of operations. The conditions placed on the regulatory authority are—if the regulatory authority is going to approve permits for mining method other than contour and area mining—then the regulatory program must contain an inspectable contemporaneous reclamation standard for the type of mining proposed.

At a public meeting, a commenter asked OSM to state in the preamble to the final rule that schedules for other mining methods are required, and not merely authorized, under proposed § 816.101(a)(3). OSM acknowledges that the preamble to the proposed rule was not clear as to whether the development of schedules was required or merely authorized. However, the rule language, both proposed and final, is clear that regulatory authorities shall provide schedules for mining methods other than area and contour mining. OSM believes that final § 816.101(a)(3) is clear that such schedules are required and not merely authorized.

A commenter asked what OSM will do in Tennessee (a Federal program State) as a result of proposed § 816.101(a)(3) which provides for the establishment through the State program approval process of schedules for operations which are neither contour nor area operations. OSM agrees that the proposed rule language did not make it clear how, or whether, mining operations requiring schedules established by the regulatory authority are to be treated when OSM is the regulatory authority. Consequently, § 816.101(a)(3) was revised to remove the word "state" from the phrase "state regulatory authority". OSM will establish the schedules for operations on Federal or Indian lands or a Federal Program State where OSM is the regulatory authority. For example, 30 CFR 942.816(e) contains the time and distance schedules for the State of Tennessee.

3. Extensions of Time Final § 816.101(b) (Proposed as § 816.101(d))

Final § 816.101(b), authorizes the regulatory authority to extend the time allowed for backfilling and grading for the entire permit area or for a specified portion of the permit area if the permittee demonstrates, in accordance with 30 CFR 780.18(b)(3), that additional time is necessary. OSM recognizes that

not all mining operations can meet a time or distance limit set on either a national or State basis. However, the extension must be requested by the permit applicant, who must demonstrate its necessity in the permit application and it must be approved by the regulatory authority as a part of the permit process.

The 1979 rules at § 816.101(a)(1) and (3) for contour and area strip mining, respectively, made similar provision for granting additional time (44 FR 15411, March 13, 1979). The preamble to those rules indicated the regulatory authority may allow additional time for rough backfilling and grading if, for example, the permittee demonstrates that the time limit established under § 816.101(a) is too restrictive because of local conditions (44 FR 15226, March 13, 1979).

One commenter stated that the flexibility provided in proposed § 816.101(d) (Final § 816.101(b)) was needed to handle unexpected delays due to unique site specific conditions such as weather, equipment, and to protect the safety of the miners. However, the commenter also insisted that the regulations in proposed § 816.101(d) should allow the regulatory authority to grant extensions for the entire permit area, and not limit such extensions to specific portions of the permit area. Also, another commenter wanted OSM to include special provisions for seasonal operations that backfill the previous mining area during the next operating period which may be 9 months later. The commenter stated that no backfill is available until the next pit is started and that the economics of coal extraction would be destroyed by having to backfill the existing pit before the start of the next pit.

OSM adopted the suggestion to modify final § 816.101(b) to allow the regulatory authority to grant time extensions for the entire permit area instead of limiting that authority to a specified portion of the permit area. Final § 816.101(b) is to be used by the regulatory authority to grant an extension because the operator cannot meet either the national standard for area or contour mines or the State standard for other types of mines because of the site-specific conditions of the permit area. In addition, these extensions are granted through the permit process in accordance with § 780.18(b)(3). To reiterate an earlier point, extensions of time are not granted to accommodate temporary shut downs resulting from adverse weather, market condition, labor problems or similar reasons. These conditions are governed under the temporary cessation provisions of 30 CFR 816.131.

A commenter suggested adding a new subsection which would allow for a specific backfilling and grading schedule as part of a postmining land use change. The commenter wanted the regulatory authority to have the flexibility to approve schedules for specific land uses on a case-by-case basis. The commenter maintained that postmining land uses such as industrial land for utility ash disposal require detailed schedules for backfilling and grading which are outside of the norm.

Another commenter recommended extending the time and distance requirements where noncoal mining operations occur within the same pit area. The commenter cited an example where sand and clay are extracted above a seam of coal (lignite) by a different company than the one mining the lignite. Additional flexibility is required, the commenter stated, where more than one operation has valid rights in the same pit area.

OSM believes these comments illustrate why flexibility in the time and distance requirements for backfilling and grading the permit area is needed. The time and distance requirements for a permit area as those described above may be extended under final § 816.101(b) for either an entire permit area or for a portion of a permit area, whichever is appropriate, depending on specific circumstances.

4. Withdrawal of Proposed §§ 816.101(b) and 816.101(c)

OSM has withdrawn proposed §§ 816.101(b) and 816.101(c) in the final rule. Proposed § 816.101(b) would have allowed a regulatory authority to establish, subject to the State program approval process, alternative backfilling and grading schedules in lieu of those prescribed in § 816.101(a). Proposed § 816.101(c) would have allowed regulatory authorities to incorporate one of two standards governing the completion of backfilling and grading in any schedule it established. The two standards were either a time interval or distance function.

As indicated in the preamble to the proposed rule, OSM considered providing this option in response to comments received during outreach briefings in which States, in their comments regarding backfilling and grading guidelines, asked to retain discretion in determining alternative schedules. These proposed provisions would have given State regulatory authorities the flexibility to adopt backfilling and grading schedules which meet State-specific conditions, but would not have established a standard for OSM to measure the sufficiency of the alternate schedules.

These proposals are withdrawn in favor of the final rules promulgated today. OSM believes the final rule's context of national schedules for area and contour mines, State schedules for other types of mining, and permit-based exemptions, when required, for special circumstances accomplishes the goal of ensuring contemporaneous reclamation while, at the same time, providing sufficient flexibility to adapt to special circumstances. After a careful analysis of the comments to the proposed rule, OSM has concluded that all potential problems with time and distance schedules could be accommodated under the final rule's structure and the additional flexibility provided in the proposed rule was unnecessary.

5. Notice of Inquiry on Multiple Seam Mining and Mountaintop Removal Operations

On April 17, 1990, OSM published a Notice of Inquiry (NOI) in the Federal Register to provide an opportunity for public comment on whether additional regulations were needed to control the contemporaneous reclamation of multiple seam and mountaintop removal mining operations (55 FR 14319, April 17, 1990). OSM published the Notice of Inquiry because of comments received on this proposed rule and reports of problems in enforcing contemporaneous reclamation at multiple seam and mountaintop sites. According to the Notice, OSM was receiving reports from field inspectors about mine sites which appeared not to be contemporaneously reclaimed. In response to those complaints, OSM solicited public comments on whether to add information requirements to the permitting rules which would require specific data on the methods of mining and schedule for completion.

Promulgation of time and distance schedules in this rule is not intended to resolve the concerns raised in the NOI concerning contemporaneous reclamation at multiple-seam operations. The issues identified in the NOI were primarily associated with enforcing contemporaneous reclamation requirements prior to the commencement of the removal of coal from the lowest permitted seam. This rule does sufficiently address, however, what it was intended to cover: Contemporaneous reclamation of sites were coal removal from the lowest permitted seam has begun. Solutions to the issue raised in the April 1991 NOI are thus beyond the scope of the

October 31, 1988 proposal, and need not be part of the basis and purpose of this rule.

Having examined the issues raised in the NOI in light of the comments received on the NOI, OSM has concluded that other existing OSM rules are sufficient to address the issues raised in the NOI. Therefore, OSM has decided not to initiate further rulemaking at this time. The sufficiency of other existing rules is explained in the following discussion. The discussion covers OSM permitting, enforcement, and oversight rules.

How Existing Regulations Ensure Contemporaneous Reclamation.—a. *Permitting.* The permitting regulations in 30 CFR 780.18(b)(1) require a detailed timetable for the completion of each major step in the reclamation plan. Paragraph 780.18(b)(3) requires a plan for backfilling, soil stabilization, compacting and grading that shows the final surface contours of the proposed permit area. In the Notice of Inquiry, OSM considered amending the permitting information regulations to require more detailed information on the mining methods and backfilling and grading sequence and schedule. Three States commenting to the Notice of Inquiry believed that OSM has adequate regulations in place to ensure contemporaneous reclamation of multiple seam and mountaintop removal operations. One commented that further rulemaking is unnecessary and not likely to accomplish the intended goal.

One commenter to the Notice of Inquiry expressed the opinion that a review of the current regulations shows that OSM has already promulgated a very comprehensive set of requirements for the permitting of surface coal mining operations to assure contemporaneous reclamation. The commenter further stated that the provision of § 780.18(b)(3) empowers State regulatory authorities to require that the operator fully remove all seams of coal and accomplish reclamation in a timely manner, in accordance with the timetable required in each permit.

OSM agrees with the commenter. In addition to § 780.18, under which operators have to submit a reclamation plan for approval, 30 CFR 780.12 and 780.14 require the submittal of operation plans and maps describing the projected progress and sequence of the permitted operation. See, e.g., § 780.14(b)(2). Plans submitted and approved under all of these sections become part of the approved permit and are enforceable by the regulatory authority. Thus regulatory authorities are empowered to assure that mining operations proceed in a timely manner and that reclamation be performed contemporaneously.

To the extent that the lack of time and distance requirements may have contributed to problems, under the final rule States are required to have time and distance schedules for all types of mining being permitted within their State. Area and contour mines have national time and distance schedules (§ 816.101(a)(1)&(2)) and other types of mines must have State schedules (§ 816.101(a)(3)).

b. *Enforcement.* OSM regulations at § 840.11(b) require four complete and 12 partial inspections of all mine sites yearly. Inspectors visiting a mine monthly can readily ascertain whether mining and reclamation is progressing contemporaneously, and whether an operator is following the approved operation and reclamation plans. Thus enforcement of the permit conditions that an operator must follow should assure that reclamation will occur in a timely manner.

c. *Oversight.* In accordance with § 842.11(a)(1), OSM has the authority to conduct inspections of surface coal mining and reclamation operations to monitor and evaluate the administration of the approved State programs.

A commenter to the Notice of Inquiry addressed the issue of additional oversight. Since the commenter believed that the issue of timely reclamation was confined to one State, they recommended that a better course of action appears to be oversight where the problem is allegedly occurring. The commenter can be assured that if additional oversight efforts are indicated by OSM's evaluation of a State's implementation of its program, these efforts will be undertaken.

d. *Multiple seam mining.* As stated earlier, the final rules provide for the application of time and distance schedules to contour and area mines with more than one seam. States may elect to have a separate schedule for multiple seam mines, which are also area or contour mines, if the State schedule adheres to the limits in § 816.101(a) (1) or (2) for those mines.

Two commenters stated that the proposed regulations failed to address multiple-seam mining. For a variety of reasons the commenters asked that the final rules include explicit standards for applying time and distance limitations to multiple-seam operations in both contour mining and mountaintop removal operations.

The same commenters contended OSM must provide, as required by the district court in its remand of the regulations governing contemporaneous reclamation, justification for its failure to establish minimum national backfilling and grading standards for multiple seam mining whether in area and contour mines or mountaintop removal operations. The commenters claimed the States, in the absence of Federal standards, will establish the weakest standards possible in order to assist their local industry.

A commenter to the Notice of Inquiry stated that when the proposed rule on time and distance schedules is adopted it will establish standards applicable to all types of mining operations, including multiple seam and mountaintop removal. The commenter continued by making the observation that many of the multiple seam coal mining operations occur within contour or area operations for which specific time and distance requirements are already in place.

As stated earlier, the time and distance schedules for contour and area mines apply whether the mine is a single or multiple seam situations. When these schedules are applied to mines with more than one seam, the time or distance standard will start with the removal of coal within the last seam. Also, if a permit applicant believes that the national schedules for contour and area mines which apply to a particular multiple seam operation are unworkable they have the ability to request a site-specific extension to the time limit under § 816.101(b).

Commenters to the proposed rules, pointed out a situation where a lower seam is permitted without any intention of mining the seam. The commenters asserted that after mining the next to last seam, the operator applies for inactive status and leaves the mountain with no reclamation.

With regard to the above comment, the time and distance limits apply when the requirement to reclaim begins. Until coal removal occurs at an area, the particular limits in § 816.101(a) do not apply. However, OSM has rules which govern not only contemporaneous reclamation but also temporary and permanent cessation and bonding all of which may apply to the type of situation described. Operators are required to follow their approved plans of operation. If they do not, the regulatory authority can step in to ensure that the rules are complied with and the violations based upon misrepresentations in such plans are corrected.

e. *Mountaintop removal operations.* Commenters to the proposed rule stated that OSM must provide justification for its failure to establish minimum national backfilling and grading standards for

mountaintop removal operations as required by the district court in its remand or to explain its failure to do so as required by the circuit court.

OSM disagrees with the characterization of the October 1984 district court opinion and the 1988 Circuit court opinion. In their discussion of contemporaneous reclamation, both courts focused on the removal of time and distance limits of area and contour mines. Neither discussion requires the establishment of such standards for mountaintop removal where such standards did not exist previously.

The commenters also maintained that the States would establish the weakest standard possible to help their industry in the absence of Federal standards. They stated that OSM must provide some national minimum standard for mountaintop removal operations so that the Congressional mandate of contemporaneous reclamation is met. In a meeting with OSM, these same commenters claimed that the rules should require State regulatory authorities to establish mountaintop removal requirements which specifically contain standards for contemporaneous reclamation.

The above commenters also acknowledged the difficulty of establishing time or distance limitations for mountaintop removal operations. They said that backfilling and grading operations and the resulting time and distance limitations for these operations will vary depending on whether multiple seams are involved and whether the spoil is being stored on the mountain, or placed entirely in fills. In either case, they concluded, the area would be graded or the surface prepared for revegetation.

Mountaintop removal operations are outside the scope of this rulemaking. However, in response to comments it is noted that the regulatory controls for mountaintop removal operations are based on the premise that the exemption from AOC is the result of an approved, specific post mining land use. The key to timely reclamation therefore is linking the mining and reclamation with the attainment of the post mining land use.

Post mining land use is, of course, evaluated on a site-by-site basis. Land use is determined by the needs of the local area as well as the compatibility of the use with the surrounding environment. Since the mountaintop removal exemption is based on the approved post mining land use and the reclamation is tied to that approval, the reclamation would be coordinated with the development of that land use.

The decision on how to achieve contemporaneous reclamation and how to inspect the permitted site to ensure adherence to timely reclamation is provided for in the 1987 amendment to the permitting requirements for mountaintop removal operations (52 FR 39182, October 21, 1987). § 785.14(c)(1)(iii)(F) requires the applicant for a mountaintop removal permit to attach a schedule to the reclamation plan as to integrate the mining operation and the reclamation with the post mining land use. To approve a permit for mountaintop removal operations a regulatory authority must evaluate that schedule against the general prescriptions covering contemporaneous reclamation in § 816.100. Following the approval of the permit, the schedule forms the inspectable basis to ensure the operation is being contemporaneously reclaimed.

In summary, mountaintop removal operations are subject to the contemporaneous reclamation standards in § 816.100. That performance standard is achieved through a site-by-site analysis of the requirements for attaining the post mining land use which formed the basis for the exemption from AOC in the permit. Each permit for mountaintop removal operations must contain a schedule, attached to the reclamation plan, which integrates the mining operation and the reclamation with achieving the post mining land use. Mine sites will be inspected against that schedule to ensure that the site is being contemporaneously reclaimed.

H. Thin or Thick Overburden

The final rules for §§ 816.104 and 816.105 remain unchanged from the rules proposed. OSM has reorganized former §§ 816.104 and 816.105 so that paragraph (a) of these sections defines thin overburden and thick overburden, respectively, and paragraph (b) contains the corresponding backfilling and grading performance standards. For convenience, the definitions of thin overburden and thick overburden in §§ 816.104(a) and 816.105(a), respectively, are discussed concurrently under the following subheading. The backfilling and grading performance standards for thin and thick overburden in § 816.104(b) and § 816.105(b), respectively, are then discussed under consecutive separate subheadings.

1. Section 816.104(a)—Definition of Thin Overburden; Section 816.105(a)—Definition of Thick Overburden

In preparing the proposed rule on §§ 816.104(a) and 816.105(a) OSM considered moving the definitions of thin overburden and thick overburden to the definition section in 30 CFR 701.5. However, because of their limited application, OSM decided to not do so. However, the term "spoil", which is used in both definitions, continues to be defined at § 701.5.

Thin overburden is defined in final § 816.104(a) as the condition where there is

> insufficient spoil and other waste materials available from the entire permit area to restore the disturbed area to its approximate original contour. Insufficient spoil and other waste materials occur where the overburden thickness times the swell factor, plus the thickness of other available waste materials, is less than the combined thickness of the overburden and coal bed prior to removing the coal, so that after backfilling and grading the surface configuration of the reclaimed area would not: (1) [c]losely resemble the surface configuration of the land prior to mining; or (2) [b]lend into and complement the drainage pattern of the surrounding terrain.

Final § 816.105(a) defines thick overburden as

> more than sufficient spoil and other waste materials available from the entire permit area to restore the disturbed area to its approximate original contour. More than sufficient spoil and other waste materials occur where the overburden thickness times the swell factor less the settlement exceeds the combined thickness of the overburden and coal bed prior to removing the coal, so that after backfilling and grading the surface configuration of the reclaimed area would not: (1) [c]losely resemble the surface configuration of the land prior to mining; or (2) [b]lend into and complement the drainage pattern of the surrounding terrain.

Both definitions contain three standards incorporating the requirements of sections 515(b)(3) and 701(2) of the Act. The first is whether there is sufficient overburden and, in the case of thin overburden, other waste materials, to restore the approximate original contour. The second standard is whether the resulting surface configuration closely resembles the land prior to mining. The third is whether the drainage pattern of the reclaimed area complements the surrounding terrain. OSM has adopted these standards for the reasons discussed below.

The exemptions in section 515(b)(3) of the Act are based on whether there is sufficient overburden to restore the land to AOC. Thin overburden means there is too little material to restore AOC; thick overburden means there is too much. Thus, whether a permit area qualifies for a thick or thin overburden exemption fundamentally depends on the definition of AOC.

Section 701(2) of the Act and the corresponding regulation at 30 CFR 701.5 define AOC as

that surface configuration achieved by backfilling and grading of the mined area so that the reclaimed area including any terracing or access roads, [1] closely resembles the general surface configuration of the land prior to mining and [2] blends into and complements the drainage pattern of the surrounding terrain, with all highwalls and spoil piles eliminated * * *.

Under this definition the two principal standards for determining AOC are whether the surface configuration of the reclaimed area would (1) closely resemble the surface configuration of the land prior to mining; and (2) blend into and complement the drainage pattern of the surrounding terrain. In restoring AOC, both of these standards must be met.

The final definitions of "thin overburden" and "thick overburden" incorporate these two standards from the definition of AOC as the measure of whether the spoil and other available waste materials are sufficient to restore AOC. The definitions apply these two standards for AOC in the disjunctive, using the term or, because a failure to meet either standard would prevent the restoration of AOC, and thus establish the occurrence of thin or thick overburden.

As it did in 1983, OSM rejects the precise numerical limits which were included in the 1979 rules as being impractical for evaluating the utility of the overburden and other available waste materials to restore AOC. Defining thin and thick overburden in precise numerical terms is impractical because of the diversity of surface configurations and drainage patterns to which the final rule would apply throughout the coal mining regions of the United States. Depending on the circumstances, inflexible numerical limits might be either too loose or too stringent, and seldom ideal.

OSM's first attempt at defining thick or thin overburden relied solely on the percentage change in overburden volume. In 1977, the proposed initial program rules prescribed thick or thin overburden as existing when the final thickness exceeded 1.2 of the initial thickness for thick overburden and when the final thickness was less than 0.8 of the initial thickness for thin overburden. (42 FR 44931, September 7, 1977). However, as acknowledged in the preamble to that rule, while OSM was using a numerical value as the standard, the primary purpose of the rules were to ensure that sites met approximate original contour. (42 FR 44921, September 7, 1977).

OSM altered its position in the final initial program rule, acknowledging at that time, that the precise numerical limits were insufficient by themselves. This position is discussed in the preamble to the final initial program rule.

Some concern was expressed over the distinction between thick and thin overburden. In particular, reviewers were concerned that not all operations needed modification of the requirement to achieve AOC. The regulations have been revised to require that whether thin or thick overburden conditions exist operations must achieve AOC whenever possible. (42 FR 62645, Dec. 27, 1977).

The final initial program rule (30 CFR 715.14(f)) added the following sentence to the proposed initial program rule.

The provisions of paragraphs (g) and (h) [performance standards for thick and thin overburden] apply only when operations cannot be carried to comply with the requirements of paragraph (a) of this section to achieve AOC.

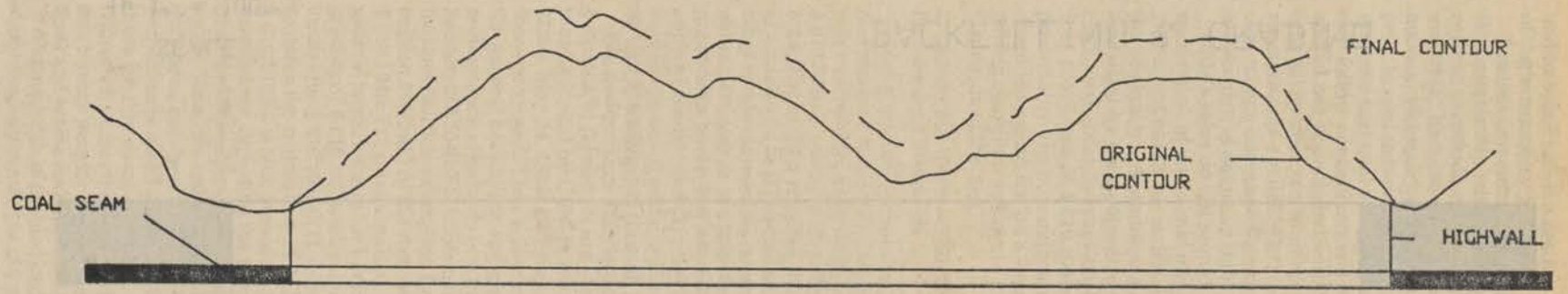
The 1979 final permanent regulatory program rules mirrored the final initial regulatory program by using the two pronged test, i.e., greater than 1.2 and achieve AOC or less than 0.8 and achieve AOC. By 1982, OSM recognized that this artificially constructed two pronged test was impractical. The numerical limits were only one part of a complex, site specific determination as to whether or not an operation could achieve AOC. In addition to being only one part of the decision there are situations in which the sites could qualify under the numerical limit but not meet the AOC criteria.

Figures 1 and 2 give examples of where reliance on precise numerical limits to determine whether thin or thick overburden conditions exist would lead to improper regulatory determinations as to whether the disturbed land should be returned to AOC. Figure 1 shows a situation where more than 20% of the premining volume has been lost but AOC can still be obtained. Figure 2 shows a situation where the post mining volume is more than 20% greater than the premining volume but AOC can still be obtained. In these situations an exemption from AOC for thin or thick overburden based on a precise 20% numerical limit would be inappropriate.

BILLING CODE 4310-05-M

AVAILABLE FILL > 120%

NO AOC VARIANCE NECESSARY



SCALE
H: 1" = 1000'
V: 1" = 100'

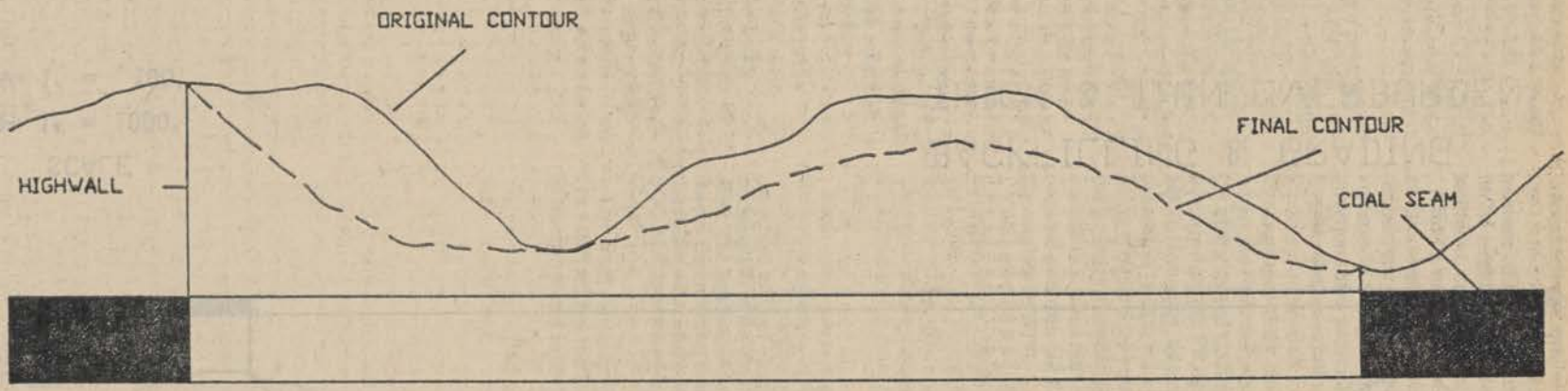
BACKFILLING & GRADING
THICK & THIN OVERBURDEN

FIGURE 1

BILLING CODE 4310-05-C

AVAILABLE FILL < 80%

NO AOC VARIANCE NECESSARY



SCALE

H: 1" = 1000'

V: 1" = 100'

BACKFILLING & GRADING

THICK AND THIN OVERBURDEN

FIGURE 2

Evaluations of post-mining surface configuration and drainage pattern involve subjective professional judgments that must be custom-tailored to approximate the terrain at any given mine. The responsible regulatory authority is best equipped to determine the sufficiency of overburden to restore AOC in its own jurisdiction on a case-by-case basis. For these reasons OSM believes it is preferable to define "thin overburden" and "thick overburden" in a way so as to conform with the standards of the Act, while giving the regulatory authority sufficient discretion to apply these standards in a sound professional manner to the diverse conditions which prevail at individual mines in each particular State.

One commenter supported OSM's deletion of the numerical standards for thin and thick overburden and the rationale that no set of rigid numerical standards could possibly apply to all types of terrain. Another commenter supported OSM's functional approach to defining thin or thick overburden and deleting the numerical limitations of the 1979 regulations. The latter commenter also claimed that section 515(b)(3) of the Act provides all the guidance regulators can be given, and that OSM should adopt that explanation in order to avoid excessive detail in the performance standards.

Another commenter objected to deleting the numerical limitations contained in the 1979 regulations for determining what constitutes thin and thick overburden. This commenter asserted that OSM's proposed rule failed to justify deletion of the 1979 standards because OSM had not presented data showing these standards to be unworkable. The commenter claimed that such data is what the Court of Appeals had in mind in remanding the 1983 regulations on thin and thick overburden.

As discussed earlier, a precise 20% numerical limit calculated from a comparison of pre and post mining volumes is an impractical test for determining the existence of a thin or thick overburden exemption because such a percentage limit cannot always accommodate the diversity of surface configurations and drainage patterns to which the final rule applies. The appropriateness of a thin or thick exemption from the requirement to return to AOC must instead be evaluated on the ability of available overburden, following backfilling and grading, to return the surface configuration of the reclaimed land to that closely resembling the surface configuration of the land prior to mining and to blend into the drainage patterns of the surrounding terrain.

Another commenter proposed that the thin overburden minimum standards be revised to include overburdens which are "thin" because of the removal of noncoal minerals by other operators prior to coal extraction. The commenter asserted that coal mining operations that follow noncoal mineral removal should not be excluded from the relaxed original contour reclamation requirements available to other surface coal mining operations where the overburden is naturally thin.

OSM's rules do not require the excavation of additional pits for the sole purpose of obtaining material to backfill the original pit. A situation such as described by the commenter should be evaluated under the previously mined area provisions of § 816.106, since, presumably, the noncoal mining operation would not be a "surface coal mining operation subject to the standards of the Act."

2. Section 816.104(b)—Thin Overburden Performance Standards

Final § 816.104(b) contains the performance standards that apply where thin overburden, as defined in § 816.104(a), occurs within the permit area. The section requires the permittee at a minimum to (1) use all spoil and other waste materials available from the entire permit area to attain the lowest practicable grade, but not more than the angle of repose; and (2) meet the general backfilling and grading requirements of 30 CFR 816.102 (a)(2) through (j).

The performance standards in § 816.104(b) (1) and (2) are identical to those adopted by OSM in 1983 (48 FR 23369, May 24, 1983) and are identical to those proposed. They will complement the general backfilling and grading performance standards in § 816.102. Section 816.104(b)(1) implements the thin overburden exemption found at section 515(b)(3) of the Act, while § 816.104(b)(2) stipulates that all of the general requirements for backfilling and grading of § 816.102 are applicable except for § 816.102(a)(1), which requires the restoration of AOC, and § 816.102(k), which provides exemptions, including the thin overburden exemption that do not apply. Thus, the only practical difference between the general performance standards in § 816.102 and those for thin overburden in § 816.104(b) (1) and (2) is that the latter section establishes priority for the use of limited spoil and waste material in reclamation.

A commenter expressed concern about the requirement to place spoil so as to achieve the lowest practicable grade in §§ 816.104(b) and 816.105(b). The commenter interpreted lowest practicable grade to mean flat and pointed out that flat land may reduce landscape diversity, which reduces wildlife habitat, and may be geomorphically incompatible with upstream and downstream drainage characteristics. The commenter stated that § 515(b)(3) of the Act has a built-in contradiction (i.e., requires spoil be backfilled to "the lowest practicable grade" in order to achieve "an ecologically sound land use compatible with the surrounding region"). The commenter wanted the regulations to resolve this conflict and require backfilling in a manner compatible with the approved postmining land use and surrounding undisturbed land.

OSM agrees that "flat land" may not resemble the general configuration of the land prior to mining or complement the drainage pattern of the surrounding terrain. Nevertheless, the provisions of § 816.104(b) and 105(b), as taken from section 515(b)(3) of the Act, require the backfilled area to attain the lowest practicable grade, but not more than the angle of repose. The phrase "lowest practicable grade" does not require flat land. It requires the lowest grade that is compatible with the surrounding terrain. In describing reclamation in a thin overburden situation, Congress indicated that the final regrading of the mine site should resemble the original landscape. H.R. No. 95–218, 95th Cong., 1st Sess. 103 (1977). Thus, the regulations already do what the commenter wishes them to do.

3. Section 816.105(b)—Thick Overburden Performance Standards

Final § 816.105(b) contains the performance standards that apply where thick overburden, as defined in § 816.105(a), occurs within the permit area.

Where the reclamation plan indicates the occurrence of thick overburden, § 816.105(b) requires the permittee at a minimum to (1) restore the approximate original contour and then use the remaining spoil and other waste materials to attain the lowest practicable grade, but not more than the angle of repose; (2) meet the general backfilling and grading requirements of 30 CFR 816.102(a)(2) through (j); and (3) dispose of any excess spoil in accordance with 30 CFR 816.71 through 816.74.

The performance standards in § 816.105(b)(1) through (3) are identical to those adopted by OSM in 1983 (48 FR 23369, May 24, 1983), and as proposed. They complement the general backfilling

and grading performance standards in § 816.102. Section 816.105(b)(1) implements the thick overburden exemption found at section 515(b)(3) of the Act, while § 816.105(b)(2) provides that all of the general requirements for backfilling and grading of § 816.102 are applicable. Section 816.105(b)(3) references the former regulations governing the disposal of excess spoil, and ensures that all spoil and other waste materials that would exceed the angle of repose are disposed of in accordance with the requirements of the Act.

The only practicable differences between the general performance standards in § 816.102 and those for thick overburden in § 816.105(b) are that under the latter (1) after AOC is restored the permittee may continue to use any remaining spoil and other waste materials to attain the lowest practicable grade, but not more than the angle of repose; and (2) the permittee must dispose of any excess spoil in accordance with § § 816.71 through 816.74.

I. Sections 816.133(d) and 817.133(d) AOC Variances

Final § 816.133(d), which is identical to proposed § 817.133(d), contains criteria for granting a variance from the requirement to restore disturbed areas to their approximate original contour. Included in paragraph (d)(1) is the stipulation that the variance be granted in accordance with § 785.16, thus limiting such variances to steep slope areas. Final § 785.16 renders the previous suspension of § 816.133(d) void, as it was based upon the suspension of former § 785.16.

A commenter recommended that § 816.133(d) be further clarified by adding language to limit its application to steep slope mining operations.

OSM disagrees. There is no need for additional language in § 816.133(d) to clarify that the section is limited in applicability to steep slope mining operations. That fact is indicated by the cross-reference to § 785.16 found at § 816.133(d)(1). Surface coal mining operations which qualify for a variance from AOC requirements under this section are obligated to adhere to § 785.16 which limits variances for steep slope operations.

III. Procedural Matters

A. Effect in Federal Program States and on Indian Lands

The rule applies through cross-referencing to those States with Federal programs. This includes California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for these States appear at 30 CFR parts 905, 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. The rule also applies, through cross-referencing, to Indian lands under the Federal program for Indian lands as provided in 30 CFR part 750.

B. Effect on State Programs

Following promulgation of this final rule, OSM will evaluate permanent State regulatory programs approved under section 503 of the Act to determine whether any changes in these programs will be necessary. If the Director determines that certain State program provisions should be amended in order to be made no less effective than the revised Federal rules, the individual States will be notified in accordance with the provisions of 30 CFR 732.17.

C. Federal Paperwork Reduction Act

This rule does not contain collections of information which require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

D. Executive Order 12291 and Regulatory Flexibility Act

The Department of the Interior has determined that the proposed rule is not a major rule under the criteria of Executive Order 12291 (February 17, 1981), and certifies that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The rule would affect a relatively small number of surface coal mining operations. The rule does not distinguish between small and large entities. The economic effects of the proposed rule are estimated to be minor, and no incremental economic effects are anticipated as a result of the rule.

E. National Environmental Policy Act

OSM has prepared environmental assessments and has made a finding that the final rules will not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C). The environmental assessments are on file in the OSM Administrative Record, room 5131, 1100 L Street, NW., Washington, DC.

F. Agency Approval

Section 516(a) requires that, with regard to rules directed toward the surface effects of underground mining, OSM must obtain written concurrence from the head of the department which administers the Federal Mine Safety and Health Act of 1977, the successor to the Federal Coal Mine Health and Safety Act of 1969. OSM has obtained the written concurrence of the Assistance Secretary for Mine Safety and Health, U.S. Department of Labor.

G. Author

The final author of this rule is Mr. Dennis M. Hunter, Jr., Chief, Research and Technical Standards Branch, Office of Surface Mining Reclamation and Enforcement.

List of Subjects

30 CFR Part 761

Historic preservation, National forests, National parks, National trails system, National wild and scenic rivers system, Surface mining, Underground mining, Wilderness areas, Wildlife refuges.

30 CFR Part 780

Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 784

Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 785

Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 816

Environmental protection, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 817

Environmental protection, Reporting and recordkeeping requirements, Underground mining.

Accordingly, 30 CFR Parts 761, 780, 784, 785, 816 and 817 are amended as set forth below:

Dated: October 21, 1991.

David O'Neal,

Assistant Secretary—Land and Minerals Management.

PART 761—AREAS DESIGNATED BY ACT OF CONGRESS

1. The authority citation for part 761 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

§ 761.5 [Amended]

2. Section 761.5 is amended by removing from the definition of Significant recreational, timber, economic, or other values incompatible with surface coal mining operations the

phrase "beyond an operator's ability to repair or restore."

PART 780—SURFACE MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENT FOR RECLAMATION AND OPERATION PLAN

3. The authority citation for part 780 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*, as amended; sec. 115 of Pub. L. 98–146, 30 U.S.C. 1257; 16 U.S.C. 470 *et seq.*; and Pub. L. 100–34.

§ 780.14 [Amended]

4. Section 780.14 paragraph (c) is amended by adding a comma and the citation "816.74(c)" after the citation "816.73(c)" in the first sentence.

§ 780.35 [Amended]

5. Section 780.35 paragraph (b) introductory text is amended by adding the words "except for the disposal of excess spoil on pre existing benches," to the beginning of the sentence.

PART 784—UNDERGROUND MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR RECLAMATION AND OPERATION PLAN

6. The authority citation for part 784 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*, as amended; sec. 115 of Pub. L. 98–146, 30 U.S.C. 1257; 16 U.S.C. 470 *et seq.*; and Pub. L. 100–34.

§ 784.23 [Amended]

7. Section 784.23 paragraph (c) is amended by adding a comma and the term "817.74(c)" after the term "817.73(c)" in the first sentence.

PART 785—REQUIREMENTS FOR PERMITS FOR SPECIAL CATEGORIES OF MINING

8. the authority citation for part 785 is revised to read as follows:

Authority: 30 U.S.C. 1201 et seq., as amended, and Pub. L. 100–34.

§ 785.16 [Amended]

9. The suspension of § 785.16, published in the Federal Register of November 20, 1986 (51 FR 41961), is removed effective January 16, 1992.

10. Section 785.16 is amended by revising the heading and the first sentence of paragraph (a) to read as follows:

§ 785.16 Permits incorporating variances from approximate original contour restoration requirements for steep slope mining.

(a) The regulatory authority may issue a permit for non-mountaintop removal, steep slope, surface coal mining and reclamation operations which includes a variance from the requirements to restore the disturbed areas to their approximate original contour that are contained in §§ 816.102, 816.104, 816.105, and 816.107, or 817.102 and 817.107 of this chapter. * * *

* * * * * * *

PART 816—PERMANENT PROGRAM PERFORMANCE STANDARDS—SURFACE MINING ACTIVITIES

11. The authority citation for part 816 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 et seq.), and Pub. L. 100–34, unless otherwise noted.

§ 816.74 [Amended]

12. Section 816.74 is amended by redesignating paragraph (e) as paragraph (h); by adding paragraphs (e), (f) and (g); and by revising paragraphs (a), (b), (c), and (d), to read as follows:

§ 816.74 Disposal of excess spoil: Preexisting benches.

(a) The regulatory authority may approve the disposal of excess spoil through placement on a preexisting bench if the affected portion of the preexisting bench is permitted and the standards set forth in §§ 816.102(c), (e) through (h), and (j), and the requirements of this section are met.

(b) All vegetation and organic materials shall be removed from the affected portion of the preexisting bench prior to placement of the excess spoil. Any available topsoil on the bench shall be removed, stored and redistributed in accordance with § 816.22 of this part. Substitute or supplemental materials may be used in accordance with § 816.22(b) of this part.

(c) The fill shall be designed and constructed using current, prudent engineering practices. The design will be certified by a registered professional engineer. The spoil shall be placed on the solid portion of the bench in a controlled manner and concurrently compacted as necessary to attain a long term static safety factor of 1.3 for all portions of the fill. Any spoil deposited on any fill portion of the bench will be treated as excess spoil fill under § 816.71.

(d) The preexisting bench shall be backfilled and graded to—

(1) Achieve the most moderate slope possible which does not exceed the angle of repose;

(2) Eliminate the highwall to the maximum extent technically practical;

(3) Minimize erosion and water pollution both on and off the site; and

(4) If the disposal area contains springs, natural or manmade water courses, or wet weather seeps, the fill design shall include diversions and underdrains as necessary to control erosion, prevent water infiltration into the fill, and ensure stability.

(e) All disturbed areas, including diversion channels that are not riprapped or otherwise protected, shall be revegetated upon completion of construction.

(f) Permanent impoundments may not be constructed on preexisting benches backfilled with excess spoil under this regulation.

(g) Final configuration of the backfill must be compatible with the natural drainage patterns and the surrounding area, and support the approved postmining land use.

* * * * *

13. Section 816.81 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 816.81 Coal mine waste: General Requirements.

(a) *General.* All coal mine waste disposed of in an area other than the mine workings or excavations shall be placed in new or existing disposal areas within a permit area, which are approved by the regulatory authority for this purpose. Coal mine waste shall be hauled or conveyed and placed for final placement in a controlled manner to—

* * * * *

14. Section 816.89 is amended by removing paragraph (d).

15. Section 816.100 is amended by removing the last sentence.

16. Section § 816.101 is added to read as follows:

§ 816.101 Backfilling and grading: Time and distance requirements.

(a) Except as provided in paragraph (b) of this section, rough backfilling and grading for surface mining activities shall be completed according to one of the following schedules:

(1) Contour mining. Within 60 days or 1,500 linear feet following coal removal;

(2) Area mining. Within 180 days following coal removal, and not more than four spoil ridges behind the pit being worked, the spoil from the active pit constituting the first ridge; or

(3) Other surface mining methods. In accordance with the schedule established by the regulatory authority. For States with approved State programs, schedules are subject to the State program approval process.

(b) The regulatory authority may extend the time allowed for rough backfilling and grading for the entire permit area or for a specified portion of the permit area if the permittee demonstrates in accordance with § 780.18(b)(3) of this chapter that additional time is necessary.

17. Section 816.104 is revised to read as follows:

§ 816.104 Backfilling and grading: Thin overburden.

(a) *Definition.* Thin overburden means insufficient spoil and other waste materials available from the entire permit area to restore the disturbed area to its approximate original contour. Insufficient spoil and other waste materials occur where the overburden thickness times the swell factor, plus the thickness of other available waste materials, is less than the combined thickness of the overburden and coal bed prior to removing the coal, so that after backfilling and grading the surface configuration of the reclaimed area would not:

(1) Closely resemble the surface configuration of the land prior to mining; or

(2) Blend into and complement the drainage pattern of the surrounding terrain.

(b) *Performance standards.* Where thin overburden occurs within the permit area, the permittee at a minimum shall:

(1) Use all spoil and other waste materials available from the entire permit area to attain the lowest practicable grade, but not more than the angle of repose; and

(2) Meet the requirements of §§ 816.102(a)(2) through (j) of this part.

18. Section 816.105 is revised to read as follows:

§ 816.105 Backfilling and grading: Thick overburden.

(a) *Definition.* Thick overburden means more than sufficient spoil and other waste materials available from the entire permit area to restore the disturbed area to its approximate original contour. More than sufficient spoil and other waste materials occur where the overburden thickness times the swell factor exceeds the combined thickness of the overburden and coal bed prior to removing the coal, so that after backfilling and grading the surface configuration of the reclaimed area would not:

(1) Closely resemble the surface configuration of the land prior to mining; or

(2) Blend into and complement the drainage pattern of the surrounding terrain.

(b) *Performance standards.* Where thick overburden occurs within the permit area, the permittee at a minimum shall:

(1) Restore the approximate original contour and then use the remaining spoil and other waste materials to attain the lowest practicable grade, but not more than the angle of repose;

(2) Meet the requirements of §§ 816.102(a)(2) through (j) of this part; and

(3) Dispose of any excess spoil in accordance with §§ 816.71 through 816.74 of this part.

§ 816.133 [Amended]

19. In § 816.133, the suspension of paragraph (d) is removed.

PART 817—PERMANENT PROGRAM PERFORMANCE STANDARDS—UNDERGROUND MINING ACTIVITIES

20. The authority citation for part 817 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 et seq.), and Pub. L. 100–34, unless otherwise noted.

§ 817.74 [Amended]

21. Section 817.74 is amended by redesignating paragraph (e) as paragraph (h); by adding paragraphs (e), (f) and (g); and by revising paragraphs (a), (b), (c), and (d), to read as follows:

§ 817.74 Disposal of excess spoil: Preexisting benches.

(a) The regulatory authority may approve the disposal of excess spoil through placement on a preexisting bench if the affected portion of the preexisting bench is permitted and the standards set forth in § 817.102 (c), (e) through (h), and (j), and the requirements of this section are met.

(b) All vegetation and organic materials shall be removed from the affected portion of the preexisting bench prior to placement of the excess spoil. Any available topsoil on the bench shall be removed, stored and redistributed in accordance with § 817.22 of this part. Substitute or supplemental materials may be used in accordance with § 817.22(b) of this part.

(c) The fill shall be designed and constructed using current, prudent engineering practices. The design will be certified by a registered professional engineer. The spoil shall be placed on the solid portion of the bench in a controlled manner and concurrently compacted as necessary to attain a long term static safety factor of 1.3 for all portions of the fill. Any spoil deposited on any fill portion of the bench will be treated as excess spoil fill under § 817.71.

(d) The preexisting bench shall be backfilled and graded to—

(1) Achieve the most moderate slope possible which does not exceed the angle of repose;

(2) Eliminate the highwall to the maximum extent technically practical;

(3) Minimize erosion and water pollution both on and off the site; and

(4) If the disposal area contains springs, natural or manmade water courses, or wet weather seeps, the fill design shall include diversions and underdrains as necessary to control erosion, prevent water infiltration into the fill, and ensure stability.

(e) All disturbed areas, including diversion channels that are not riprapped or otherwise protected, shall be revegetated upon completion of construction.

(f) Permanent impoundments may not be constructed on preexisting benches backfilled with excess spoil under this regulation.

(g) Final configuration of the backfill must be compatible with the natural drainage patterns and the surrounding area, and support the approved postmining land use.

* * * * *

22. Section 817.81 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 817.81 Coal mine waste: General requirements.

(a) *General.* All coal mine waste disposed of in an area other than the mine workings or excavations shall be placed in new or existing disposal areas within a permit area, which are approved by the regulatory authority for this purpose. Coal mine waste shall be hauled or conveyed and placed for final placement in a controlled manner to—

* * * * *

23. Section 817.89 is amended by removing paragraph (d).

24. In § 817.133, the suspension of paragraph (d) is removed.

[FR Doc. 91–29959 Filed 12–16–91; 8:45 am]
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federal register

Tuesday
December 17, 1991

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 1, et al.
Airspace Reclassification; Final Rule

DEPARTMENT OF TRANSPORTATION

14 CFR Parts 1, 11, 45, 61, 65, 71, 75, 91, 93, 101, 103, 105, 121, 127, 135, 137, 139, and 171

[Docket No. 24456; Amendment Nos. 1-38, 11-35, 45-21, 61-92, 65-36, 71-14, 75-5, 91-227, 93-63, 101-5, 103-4, 105-10, 121-226, 127-44, 135-40, 137-14, 139-18, and 171-16]

RIN 2120-AB95

Airspace Reclassification

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Aviation Regulations (FAR) to adopt certain recommendations of the National Airspace Review (NAR) concerning changes to regulations and procedures in regard to airspace classifications. These changes are intended to: (1) Simplify airspace designations; (2) achieve international commonality of airspace designations; (3) increase standardization of equipment requirements for operations in various classifications of airspace; (4) describe appropriate pilot certificate requirements, visual flight rules (VFR) visibility and distance from cloud rules, and air traffic services offered in each class of airspace; and (5) satisfy the responsibilities of the United States as a member of the International Civil Aviation Organization (ICAO). The final rule also amends the requirement for minimum distance from clouds in certain airspace areas and the requirements for communications with air traffic control (ATC) in certain airspace areas; eliminates airport radar service areas (ARSAs), control zones, and terminal control areas (TCAs) as airspace classifications; and eliminates the term "airport traffic area." The FAA believes simplified airspace classifications will reduce existing airspace complexity and thereby enhance safety.

EFFECTIVE DATE: These regulations become effective September 16, 1993, except that §§ 11.61(c), 91.215(d), 71.601, 71.603, 71.605, 71.607, and 71.609 and Part 75 become effective December 12, 1991, and except that amendatory instruction number 20, § 71.1, is effective as of December 17, 1991 through September 15, 1993, and that §§ 71.11 and 71.19 become effective October 15, 1992. The incorporation by reference of FAA Order 7400.7 in § 71.1 (amendatory instruction number 20) is approved by the Director of the Federal Register as of December 17, 1991, through September 15, 1993. The incorporation by reference of FAA Order 7400.9 in § 71.1 (amendatory instruction number 24) is approved by the Director of the Federal Register as of September 16, 1993 through September 15, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. William M. Mosley, Air Traffic Rules Branch, ATP-230, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267-9251.

SUPPLEMENTARY INFORMATION:

Background

On April 22, 1982, the NAR plan was published in the **Federal Register** (47 FR 17448). The plan encompassed a review of airspace use and the procedural aspects of the ATC system. Organizations participating with the FAA in the NAR included: Aircraft Owners and Pilots Association (AOPA), Air Line Pilots Association (ALPA), Air Transport Association (ATA), Department of Defense (DOD), Experimental Aircraft Association (EAA), Helicopter Association International (HAI), National Association of State Aviation Officials (NASAO), National Business Aircraft Association (NBAA), and Regional Airline Association (RAA).

The main objectives of the NAR were to:

(1) Develop and incorporate a more efficient relationship between traffic flows, airspace allocation, and system capacity in the ATC system. This relationship will involve the use of improved air traffic flow management to maximize system capacity and to improve airspace management.

(2) Review and eliminate, wherever practicable, governmental restraints to system efficiency thereby reducing complexity and simplifying the ATC system.

(3) Revalidate ATC services within the National Airspace System (NAS) with respect to state-of-the-art and future technological improvements.

In furtherance of the foregoing objectives, several NAR task groups were organized and assigned to review various issues associated with airspace classifications and ATC procedures, pilot certification requirements, and aircraft equipment and operating requirements in the different categories of airspace areas. The recommendations formed the basis of three separate advance notices of proposed rulemaking (ANPRM): Notice No. 85-4, Terminal Airspace Reclassification (50 FR 5055; February 2, 1985); Notice No. 85-5, Airspace Reclassification/Services/Requirements (50 FR 5046; February 2, 1985); and Notice No. 85-15, Controlled Airspace Designations in International Airspace (50 FR 30798; July 7, 1985).

On March 12, 1990, ICAO through its Air Navigation Commission (ANC) formally adopted the airspace classification concept in amendment No. 33 to annex 11. The airspace classifications adopted by ICAO, along with the nearest equivalent U.S. airspace designations, are summarized as follows:

Class A Airspace (U.S. Positive Control Areas)

All operations must be conducted under instrument flight rules (IFR) and are subject to ATC clearances and instructions. ATC separation is provided to all aircraft.

Class B Airspace (U.S. Terminal Control Areas)

Operations may be conducted under IFR, special visual flight rules (SVFR), or VFR. However, all aircraft are subject to ATC clearances and instructions. ATC separation is provided to all aircraft.

Class C Airspace (U.S. Airport Radar Service Areas)

Operations may be conducted under IFR, SVFR, or VFR; however, all aircraft are subject to ATC clearances and instructions. ATC separation is provided to all aircraft operating under IFR or SVFR and, as necessary, to any aircraft operating under VFR when any aircraft operating under IFR is involved. All VFR operations will be provided with safety alerts and, upon request, conflict resolution instructions.

Class D Airspace (U.S. Control Zones for Airports with Operating Control Towers and Airport Traffic Areas that are not associated with a TCA or an ARSA)

Operations may be conducted under IFR, SVFR, or VFR; however, all aircraft are subject to ATC clearances and instructions. ATC separation is provided to aircraft operating under IFR or SVFR only. All traffic will receive safety alerts and, on pilot request, conflict resolution instructions.

Class E Airspace (U.S. General Controlled Airspace)

Operations may be conducted under IFR, SVFR, or VFR. ATC separation is provided only to aircraft operating under IFR and SVFR within a surface area. As far as practical, ATC may provide safety alerts to aircraft operating under VFR.

Class F Airspace (U.S. Has No Equivalent)

Operations may be conducted under IFR or VFR. ATC separation will be provided, so far as practical, to aircraft operating under IFR.

Class G Airspace (U.S. Uncontrolled Airspace)

Operations may be conducted under IFR or VFR. ATC separation is not provided.

Discussion of the Amendments and Public Comments

This final rule is based on Notice of Proposed Rulemaking (NPRM) No. 89–28 (54 FR 42916; October 18, 1989). The rule amends parts 1, 11, 45, 61, 65, 71, 75, 91, 93, 101, 103, 105, 121, 127, 135, 137, 139, and 171 and Special Federal Aviation Regulations (SFAR) 51–1, 60, and 62. These parts either incorporate airspace designations and operating rules or amend the existing rule to meet the new classification language.

Amendments to part 1 delete the definition of an "airport traffic area" and add definitions of "Special VFR conditions" and "Special VFR operations."

The amendments to part 71 establish a new subpart M—Jet Routes and Area High Routes that includes the existing rules in part 75 as of December 17, 1991; revise §§ 71.11 and 71.19 as of October 15, 1992; and revise all of part 71 to reclassify U.S. airspace in accordance with the ICAO designations as of September 16, 1993. (Further information on the amendments to part 71 appears in this discussion under Revisions to Part 71.) Under this amendment the positive control areas (PCAs), jet routes, and area high routes are reclassified as Class A airspace areas; TCAs are reclassified as Class B airspace areas; ARSAs are reclassified as Class C airspace areas; control zones for airports with operating control towers and airport traffic areas that are not associated with the primary airport of a TCA or an ARSA are reclassified as Class D airspace areas; all Federal airways, the Continental Control Area, control areas associated with jet routes outside the Continental Control Area, additional control areas, control area extensions, control zones for airports without operating control towers, transition areas, and area low routes are reclassified as Class E airspace areas; and airspace which is not otherwise designated as the Continental Control Area, a control area, a control zone, a terminal control area, an airport radar service area, a transition area, or special use airspace is reclassified as Class G airspace. Because airport traffic areas are not classified as airspace areas, this amendment establishes controlled airspace for airports with operating control towers, but without control zones.

Part 75 is removed and reserved. The existing information is transferred to new subpart M of existing part 71.

Amendments to Part 91 change terminology to integrate the adopted airspace classifications into corresponding part 91 operating rules. In addition, the distance from cloud requirements in Class B airspace areas for VFR operations are amended to require a pilot to remain clear of clouds instead of the current requirements of 500 feet below, 1,000 feet above, and 2,000 feet horizontal from clouds in TCAs.

Section 91.215(d) is amended by relaxing current restraints on ATC in authorizing deviations to operators of aircraft that are not equipped with transponders. The amendment clarifies that the ATC facility having jurisdiction over the airspace concerned is permitted to authorize deviations from the transponder requirements in § 91.215(b) and that a request for a deviation due to an inoperative transponder or an operating transponder without operating automatic pressure altitude reporting equipment having Mode C capability may be made at any time. To provide maximum flexibility to ATC and aircraft operators, this amendment has an effective date of December 17, 1991.

Amendments to parts 11, 45, 61, 65, 93, 101, 103, 105, 121, 127, 135, 137, 139, and 171 change the terminology to integrate the adopted airspace classifications into respective regulations that refer to those airspace assignments and operating rules. In addition, § 11.61(c) is amended to meet an administrative change within the FAA for titles of persons under the term "Director."

The final rule includes modifications to the proposed rules based on amendments to the FAR that have become effective since the publication of NPRM No. 89–28. The section numbers to part 91 are changed to match the section numbers designated by amendment No. 91–211, Revision of General Operating and Flight Rules (54 FR 34292; August 19, 1989). Sections 91.129 and 91.130 are modified to include revisions to § 91.130 by amendment No. 91–215, Airport Radar Service Area (ARSA) Communication Requirement (55 FR 17736; April 26, 1990). Section 91.131(c) is modified to include revisions from amendment No. 91–216, Navigational Equipment Requirement in a Terminal Control Area (TCA) and Visual Flight Rules (VFR) Operations (55 FR 24822; June 18, 1990). Section 91.117(a) is modified to include revision by amendment No. 91–219, Revision to General Operating and Flight Rules (55 FR 34707; August 24, 1990).

Section 91.155(b)(1) is modified to include a revision by amendment No. 91–224, Inapplicability of Basic VFR Weather Minimums for Helicopter Operations (56 FR 48088; September 23, 1991). Section 91.155(c) was revised by amendment No. 91–213, Night-Visual Flight Rules Visibility and Distance from Cloud Minimums (55 FR 10610; March 22, 1990) and was corrected on July 19, 1990 (55 FR 29552) and November 13, 1990 (55 FR 47309).

In this amendment, the FAA does not adopt the proposal to lower the Continental Control Area to 1,200 feet above the surface and to establish the United States Control Area as proposed in NPRM No. 88–2. The FAA will not adopt this proposal and the regulatory agenda will be revised to delete the U.S. Control Area project.

On October 4, 1990, the FAA established SFAR No. 60—Air Traffic Control System Emergency Operations (55 FR 40758) and on December 5, 1990, the FAA established SFAR No. 62—Suspension of Certain Aircraft Operations from the Transponder with Automatic Pressure Altitude Reporting Capability Requirement (55 FR 50302). These SFARs are revised by replacing references to such terms as "terminal control area" with "Class B airspace area" to integrate the appropriate airspace classification.

Obsolete clauses in the existing rule are deleted and typographical errors in the proposal are corrected. The final rule also revises affected paragraphs of the existing rule requiring modification as a result of the rulemaking action but not included in NPRM No. 89–28. The modifications to these paragraphs replace such terms as "terminal control area" and "control zone" with language to integrate the appropriate airspace classification.

Under airspace reclassification, the Sabre U.S. Army Heliport (Tennessee) Airport Traffic Area will become a Class D airspace area; the Jacksonville, Florida, Navy Airport Traffic Area will become three separate but adjoining Class D airspace areas; and the El Toro, California, Special Air Traffic Rules will become part of the El Toro Class C airspace area. Currently, these airports operate under special air traffic rules in subparts N, O, and R of part 93. To achieve a goal of airspace reclassification, which is to simplify airspace, the existing rules for these airspace areas are to be deleted as of

September 16, 1993. Therefore, this amendment removes and reserves subparts N, O, and R of part 93 as of September 16, 1993.

Revisions to Part 71

Part 71 is revised in three stages.

The first revision creates a new subpart M—Jet Routes and Area High Routes, comprising §§ 71.601, 71.603, 71.605, 71.607, and 71.609. Under this amendment, the existing information in part 75 is transferred to new subpart M of part 71. Since this amendment does not change any operating rules, it is effective December 17, 1991. Section 75.17, Bearings; radials; miles, is not transferred to new subpart M, because the same information is located in existing § 71.19. NPRM No. 89–28 proposed to amend existing § 75.13. The proposed language is adopted in new § 71.605. A chart comparing old part 75 and new part 71, subpart M follows.

Part 75—Establishment of Jet Routes and Area High Routes	Part 71, Subpart M—Jet Routes and Area High Routes
§ 75.1 Applicability.	§ 71.601 Applicability.
§ 75.11 Jet routes.	§ 71.603 Jet routes.
§ 75.13 Area routes above 18,000 feet MSL.	§ 71.605 Area routes above 18,000 feet MSL.
§ 75.100 Jet routes.	§ 71.607 Jet route descriptions.
§ 75.400 Area high routes.	§ 71.609 Area high route descriptions.

Sections 71.607, Jet route descriptions, and 71.609, Area high route descriptions are not set forth in the full text of this final rule. The complete listing for all jet routes and area high routes can be found in FAA Order 7400.7, Compilation of Regulations, which was last published as of April 30, 1991, and effective November 1, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this order may be obtained from the Document Inspection Facility, APA–220, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, (202) 267–3484. Copies may be inspected in Docket Number 24456 at the Federal Aviation Administration, Office of the Chief Counsel, AGC–10, room 915G, 800 Independence Avenue, SW., Washington, DC 20591 weekdays between 8:30 a.m. and 5 p.m. or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC The part 75 sections referenced in FAA Order 7400.7 will be redesignated as part 71 sections in the next revision to FAA Order 7400.7.

The second revision amends existing § 71.11, Control zone, and § 71.19, Bearings; radials; miles, and is effective October 15, 1992. This revision relates to the FAA's parallel reviews of certain airspace areas. The revision to § 71.11 permits the Administrator to terminate the vertical limit of a control zone at a specified altitude. The revision to § 71.19 provides for the conversion from statute miles to nautical miles and consists of the same language as § 71.7 that is effective September 16, 1993. More detail on the review of certain airspace areas is found under the title Implementation of Airspace Reclassification.

The third revision to part 71 establishes a new part 71 that includes the adopted airspace designations. This amendment, which is effective September 16, 1993, transfers the current sections of existing part 71, including subpart M—Jet Routes and Area High Routes, to this new part 71. The following table lists the sections of existing part 71, including subpart M and the corresponding sections in the new part 71 that are effective September 16, 1993. Subparts B through K and §§ 71.501(b), 71.607, and 71.609, which list airspace descriptions, are not set forth in the full text of this final rule. The complete listing for these airspace designations can be found in FAA Order 7400.9, Airspace Reclassification, which is effective September 16, 1993. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of this order may be obtained from the Document Inspection Facility, APA–220, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, (202) 267–3484. Copies may be inspected in Docket Number 24456 at the Federal Aviation Administration, Office of the Chief Counsel, AGC–10, room 915G, 800 Independence Avenue, SW., Washington, DC 20591 weekdays between 8:30 a.m. and 5 p.m. or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

Existing Part 71	Revised Part 71 that is effective September 16, 1993, and FAA Order 7400.9
Subpart A—General	*Subpart A—General; Class A airspace*
§ 71.1 Applicability.	§ 71.1 Airspace classification.
§ 71.3 Classification of Federal airways.	§ 71.73 Classification of Federal airways.
§ 71.5 Extent of Federal airways.	§ 71.75 Extent of Federal airways.
§ 71.6 Extent of area low routes.	§ 71.77 Extent of area low routes.
§ 71.7 Control areas.	Not applicable.
§ 71.9 Continental control area.	§ 71.71 Class E airspace.
§ 71.11 Control zones.	Not applicable.
§ 71.12 Terminal control areas.	§ 71.41 Class B airspace.
§ 71.13 Transition areas.	§ 71.71 Class E airspace.
§ 71.14 Airport radar service areas.	§ 71.51 Class C airspace.
§ 71.15 Positive control areas.	§ 71.31 Class A airspace.
§ 71.17 Reporting points.	§ 71.5 Reporting Points.
§ 71.19 Bearings; Radials; Miles.	§ 71.7 Bearings, radials, mileages.
Subpart B—Colored Federal Airways	*Subpart E—Class E Airspace*
§ 71.101 Designation.	Subpart E of FAA Order 7400.9.
§ 71.103 Green Federal airways.	Subpart E of FAA Order 7400.9.
§ 71.105 Amber Federal airways.	Subpart E of FAA Order 7400.9.
§ 71.107 Red Federal airways.	Subpart E of FAA Order 7400.9.
§ 71.109 Blue Federal airways.	Subpart E of FAA Order 7400.9.
Subpart C—VOR Federal Airways	*Subpart E—Class E Airspace*
§ 71.121 Designation.	§ 71.79 Designation of VOR Federal airways.
§ 71.123 Domestic VOR Federal airways.	Subpart E of FAA Order 7400.9.
§ 71.125 Alaskan VOR Federal airways.	Subpart E of FAA Order 7400.9.
§ 71.127 Hawaiian VOR Federal airways.	Subpart E of FAA Order 7400.9.
Subpart D—Continental Control Area	*Subpart E—Class E Airspace*
§ 71.151 Restricted areas included.	Subpart E of FAA Order 7400.9.
Subpart E—Control Areas and Control Area Extensions	*Subpart E—Class E Airspace*
§ 71.161 Designation of control areas associated with jet routes outside the continental control area.	§ 71.71 Class E airspace and Subpart E of FAA Order 7400.9.
§ 71.163 Designation of additional control areas.	§ 71.71 Class E airspace and Subpart E of FAA Order 7400.9.
§ 71.165 Designation of control areas extensions.	Subpart E of FAA Order 7400.9.
Subpart F—Control Zones	*Subpart D—Class D Airspace*
§ 71.171 Designation.	*Subpart E—Class E Airspace*
	Subpart D of FAA Order 7400.9.
	Subpart E of FAA Order 7400.9.
Subpart G—Transition Areas	*Subpart E—Class E Airspace*
§ 71.181 Designation.	Subpart E of FAA Order 7400.9.
Subpart H—Positive Control Areas	*Subpart A—General; Class A Airspace*
§ 71.193 Designation.	§ 71.33 Class A airspace areas.
Subpart I—Reporting Points	*Subpart H—Reporting Points*
§ 71.201 Designation.	§ 71.901 Applicability.
§ 71.203 Domestic low altitude reporting points.	Subpart H of FAA Order 7400.9.

Existing Part 71	Revised Part 71 that is effective September 16, 1993, and FAA Order 7400.9
§ 71.207 Domestic high altitude reporting points.	Subpart H of FAA Order 7400.9.
§ 71.209 Other domestic reporting points.	Subpart H of FAA Order 7400.9.
§ 71.211 Alaskan low altitude reporting points.	Subpart H of FAA Order 7400.9.
§ 71.213 Alaskan high altitude reporting points.	Subpart H of FAA Order 7400.9.
§ 71.215 Hawaiian reporting points.	Subpart H of FAA Order 7400.9.
Subpart J—Area Low Routes	*Subpart E—Class E Airspace*
§ 71.301 Designation.	Subpart E of FAA Order 7400.9.
Subpart K—Terminal Control Areas	*Subpart B—Class B Airspace*
§ 71.401(a) Designation.	Subpart B of FAA Order 7400.9.
§ 71.401(b) Terminal control areas.	Subpart B of FAA Order 7400.9.
Subpart L—Airport Radar Service Areas	*Subpart C—Class C Airspace*
§ 71.501 Designation.	Subpart C of FAA Order 7400.9.
Subpart M—Jet Routes and Area High Routes	*Subpart A—General; Class A Airspace*
§ 71.601 Applicability.	Not applicable.
§ 71.603 Jet routes.	Subpart A of FAA Order 7400.9.
§ 71.605 Area routes above 18,000 feet MSL.	Subpart A of FAA Order 7400.9.
§ 71.607 Jet route descriptions.	Subpart A of FAA Order 7400.9.
§ 71.609 Area high route descriptions.	Subpart A of FAA Order 7400.9.

Discussion of Comments

A total of 205 commenters submitted comments to Docket No. 24456 on NPRM No. 89–28. The FAA considered these comments in the adoption of this rule and changes to the proposals were made accordingly. Some comments did not specifically apply to any particular proposal addressed in NPRM No. 89–28. These comments related to the requirements for a transponder with Mode C capabilities, the FAA's anti-drug program, and the proposed TCA for the Washington-Baltimore metropolitan area.

Comments submitted on NPRM No. 89–28 reflect the views of a broad spectrum of the aviation public. The commenters included individuals as well as organizations representing commercial and general aviation pilots. Organizations that commented on NPRM No. 89–28 include: AOPA, ALPA, Air Traffic Control Association (ATCA), ATA, Alaska Airmen's Association, Arizona Pilots Association, Canadian Owners and Pilots Association (COPA), EAA, Ohio Department of Transportation, and Soaring Society of America (SSA).

The following is a discussion of issues addressed in the comments in accordance with the reclassification effort and each classification of airspace. A general division entitled, Additional Comments, addresses issues that do not affect a specific airspace classification. Each discussion includes a description of the final amendment and an explanation of the FAA's views.

Reclassification of Airspace

One hundred and forty-one comments on the proposal to reclassify U.S. airspace to meet ICAO standards were submitted. Sixty-eight supported reclassification and 69 opposed reclassification. Four commenters neither supported nor opposed the reclassification effort, but offered observations.

The 68 supporting comments include those submitted by the ATA, ATCA, and COPA. The COPA stated that on an average, approximately 60,000 general aviation aircraft cross the U.S./Canadian border each year. Some commenters stated that the proposed classifications are easier to understand than the current classifications and noted that the proposed classifications would help develop standardization. Two flight instructors commented that the proposed classifications would aid in the teaching of the airspace system to new pilots.

The 69 opposing comments include the Arizona Pilots Association, EAA, and SSA. Several comments, including EAA's, asserted that the current airspace designation names are more descriptive, and hence, easier to remember. Several comments, including one from the Arizona Pilots Association, stated that the proposal would cause confusion, while other commenters alleged that the proposal would only benefit pilots who operate internationally.

Both the SSA and the Arizona Pilots Association recommend that existing airspace nomenclature be retained and a table be included in the Airman's Information Manual (AIM) or part 91 to correlate U.S. airspace designations and ICAO equivalents.

The four comments submitted that do not directly support or oppose the proposal include those from the Alaska Airmen's Association, ALPA, and AOPA. The AOPA expressed concerns about how pilots would be reeducated during the transition phase that would precede the adoption of the proposed airspace reclassification. AOPA recommended that the FAA take five steps to ensure proper pilot education: (1) Convene a government, industry, and user meeting before the issuance of a final rule to consider the implications of final rule adoption; (2) ensure that all necessary funding is in place, including monies for the specific purpose of pilot education; (3) adopt a dual airspace system during the transition phase; (4) coordinate with the National Oceanic and Atmospheric Administration (NOAA) to ensure that all charts are printed in a timely manner; and (5) amend the flight review requirements to reflect explicitly the need to discuss airspace classifications. The FAA agrees that the aviation public needs to be educated in airspace reclassification. Therefore, the FAA has developed an education and transition program, which is discussed under "Education of the Aviation Community."

As proposed, the FAA will reclassify U.S. airspace in accordance with ICAO standards. Airspace areas, with the exception of special use airspace (SUA) designations, will be classified by a single alphabet character. The FAA believes that reclassification of U.S. airspace simplifies the airspace system, achieves international commonality, enhances aviation safety, and satisfies the responsibility of the United States as a member of ICAO.

Some commenters misunderstood the proposal on airspace reclassification. These commenters understood Class A airspace areas to be en route airspace and Class B, Class C, and Class D airspace areas to be terminal airspace. The recommended ICAO airspace classes are not based on whether the airspace area is designated for "en route" or "terminal" operations, but rather on other factors that include type of operation (i.e., IFR, VFR) and ATC services provided. (The table below lists the new airspace classifications, its equivalent in the existing airspace classification, and its features, which would apply to terminal and en route airspace areas.) For example, under this rule Class C airspace is designated in terminal areas. Class C airspace in another country could be designated in en route areas. However, the type of operation, ATC services provided, minimum pilot qualifications, two-way radio requirements, and VFR minimum visibility and distance from cloud requirements in that country's Class C airspace will be similar to the Class C airspace areas designated in the United States. As adopted by the FAA, Class A airspace areas are designated in positive control en route areas; Class B, Class C, and Class D airspace areas are designated in terminal areas; and Class E airspace areas are designated in both en route (low altitude) and terminal

areas. However, the rules are written in a manner that the classes of airspace will not be limited to terminal or en route airspace areas. For example, if a regulation only applies to operations in a terminal environment, the rule specifies that the airspace is "designated for an airport."

AIRSPACE CLASSIFICATIONS

Airspace features	Class A airspace	Class B airspace	Class C airspace	Class D airspace	Class E airspace	Class G airspace
Current Airspace Equivalent	Positive Control Areas.	Terminal Control Areas.	Airport Radar Service Areas.	Airport Traffic Areas and Control Zones.	General Controlled Airspace.	Uncontrolled Airspace
Operations Permitted	IFR	IFR and VFR	IFR and VFR	IFR and VFR	IFR and VFR	IFR and VFR
Entry Prerequisites	ATC clearance	ATC clearance	ATC clearance for IFR Radio contact for all.	ATC clearance for IFR Radio contact for all.	ATC clearance for IFR Radio contact for all IFR.	None
Minimum Pilot Qualifications	Instrument rating	Private or student certificate.	Student certificate	Student certificate	Student certificate	Student certificate
Two-way radio communications.	Yes	Yes	Yes	Yes	Yes for IFR operations.	No
VFR Minimum Visibility	Not applicable	3 statute miles	3 statute miles	3 statute miles	* 3 statute miles	** 1 statute mile
VFR Minimum Distance from Clouds.	Not applicable	Clear of clouds	500 feet below, 1,000 feet above, and 2,000 feet horizontal.	500 feet below, 1,000 feet above, and 2,000 feet horizontal.	* 500 feet below, 1,000 feet above, and 2,000 feet horizontal.	** 500 feet below, 1,000 feet above, and 2,000 feet horizontal
Aircraft Separation	All	All	IFR, SVFR, and runway operations.	IFR, SVFR, and runway operations.	IFR, SVFR	None
Conflict Resolution	Not applicable	Not applicable	Between IFR and VFR operations.	No	No	No
Traffic Advisories	Not applicable	Not applicable	Yes	Workload permitting	Workload permitting	Workload permitting
Safety Advisories	Yes	Yes	Yes	Yes	Yes	Yes

* Different visibility minima and distance from cloud requirements exist for operations above 10,000 feet MSL.
** Different visibility minima and distance from cloud requirements exist for night operations, operations above 10,000 feet MSL, and operations below 1,200 feet AGL.

Offshore Airspace

The FAA adopts, as proposed, the NAR recommendations NAR 3-2.1.1—Offshore Airspace Nomenclature, NAR 3-2.1.2—Offshore Control Area Uniform Base, NAR 3-2.1.3—Offshore Control Area Identification, and NAR 3-2.1.4—Offshore Airspace Classification, which consider offshore airspace areas. However, NAR 3-2.1.2, which recommends a uniform base for offshore control areas of 1,200 feet above the surface unless otherwise designated, and NAR 3-2.1.3, which recommends that offshore control areas be identified with a name as opposed to a number are contingent on the FAA's further review. (More details on the review process appear later in this document under the title Implementation of Airspace Reclassification.) Any changes to offshore airspace areas resulting from the FAA's review will be accomplished by separate rulemaking actions. The FAA's review is being conducted in compliance with Executive Order 10854, which requires FAA consultation with both the Departments of State and Defense before designating controlled international airspace. The FAA expects that most offshore airspace areas will be classified as Class E or Class A airspace areas.

Education of the Aviation Community

The FAA agrees with the comments that the aviation public needs to be educated in airspace reclassification. To ensure that the aviation community can become knowledgeable about the new airspace classifications and that aeronautical charts can be updated, the new airspace classification will not become effective until September 16, 1993.

The FAA has begun to coordinate with a task group of the Interagency Air Cartographic Committee (IACC) and the National Ocean Service (NOS), which will begin to update aeronautical charts. During the transition, the FAA will update its orders, manuals, handbooks, and advisory circulars, and will provide pilot/controller education. Significant dates in the transition process appear below with additional discussion following.

AIRSPACE RECLASSIFICATION TRANSITION

Tentative date	Event
October 15, 1992.	First sectional aeronautical charts (SAC), world aeronautical charts (WAC), and terminal aeronautical charts (TAC) are published with legends that indicate both existing and future airspace classifications.
March 4, 1993	Initial charting changes are completed for the SAC and TAC.
June 24, 1993	North Pacific, Gulf of Mexico, and Caribbean planning charts are published with legends that indicate both existing and future airspace classifications.

AIRSPACE RECLASSIFICATION TRANSITION—Continued

Tentative date	Event
August 19, 1993	Flight Case Planning and North Atlantic Route charts are published with legends that indicate existing and future airspace classifications.
September 16, 1993.	New airspace classifications become effective. All charts begin publication with legends that indicate both the new airspace classification and the former airspace classification. All related publications are updated.
March 3, 1994	First charts are published with legends that only indicate the new airspace classifications.
August 17, 1994	All charts are published with legends that only indicate the new airspace classifications.

Coordination with a task group of the IACC and the NOS will continue throughout the transition. An anticipated modification to the symbols on aeronautical charts is the addition of a segmented magenta line to represent the controlled airspace area for airports without operating control towers that extends upward from the surface (Class E airspace). A segmented blue line (which currently depicts a control zone) will denote a Class D airspace area, the controlled airspace for airports with operating control towers that are not the primary airport of a TCA or an ARSA.

The legends in aeronautical charts will include both the existing airspace classifications and the airspace classifications to be effective September 16, 1993. For example, the solid blue line that symbolizes a TCA will be followed by "TCA (Class B)." The first charts with a dual legend will be published October 15, 1992. Commencing September 16, 1993, the legends on these charts will be reversed (e.g., a solid blue line will be followed by "Class B (TCA)"). Between March 3 and August 17, 1994, the use of dual indication legends will be phased out.

Between October 1992 and March 1993, educational materials such as pocket guides, a video, and posters will be issued to instruct the aviation public on airspace reclassification. The FAA will begin to update the AIM and other publications, as well as FAA orders, manuals, handbooks, and advisory circulars that must be revised to include the new airspace classifications and an explanation of the transition and implementation procedures.

The transition and implementation of the Airspace Reclassification final rule also will include parallel reviews of certain current airspace designations to meet the new airspace classifications. A full discussion on this review appears later in this document under the title Implementation of Airspace Reclassification.

Class A Airspace

NPRM No. 89–28 proposed to reclassify the PCAs as Class A airspace areas with no other alterations to this airspace. Four commenters, including AOPA, neither supported nor opposed this classification; however, they offered comments and modifications. Some commenters stated that if the FAA adopts the Class A designation for the PCAs, Class A airspace areas should remain en route airspace and should not be lower than 18,000 feet mean sea level (MSL).

As proposed, the FAA will reclassify the PCAs as Class A airspace areas. In addition, jet routes and area high routes will be reclassified as Class A airspace areas. These airspace areas, which consist of direct courses for navigating aircraft at altitudes between 18,000 feet MSL and flight level 450, inclusive, meet the criteria of Class A airspace as adopted by ICAO.

As noted earlier, the recommended ICAO airspace classes are not based on whether the airspace area is designated for "en route" or "terminal" operations. Any new Class A airspace areas would be proposed in separate rulemaking actions.

Class B Airspace

NPRM No. 89–28 proposed to reclassify TCAs as Class B airspace areas and to amend the minimum distances by which aircraft operating under VFR must remain from clouds. The current VFR minimum distance requirements of 500 feet below, 1,000 feet above, and 2,000 feet horizontal from clouds will be amended to require that the pilot must remain clear of clouds.

One comment supports and two comments specifically oppose the proposed reclassification. Twelve comments on the proposal to amend minimum distance from clouds for VFR operations in Class B airspace areas were received. Eight of these comments support and four oppose the proposal.

The comments submitted in support of the proposal to reclassify TCAs as Class B airspace areas and to modify the minimum distances from cloud for VFR operations include those from AOPA, the Alaska Airmen's Association, EAA, and SSA. AOPA stated that the proposal "is a positive step in improvement of VFR traffic flow within" Class B airspace areas.

A commenter in support of reclassification stated that some of the areas to be classified as Class B airspace areas could be redesignated as Class C airspace areas.

The four comments submitted in opposition to the proposed amendment on distance from cloud requirements for VFR operations include a comment from ALPA. Some commenters stated that the proposal to modify the minimum distance from clouds for VFR flight in Class B airspace areas reduces the existing margin of safety. ALPA further stated that the ability of a pilot to maintain visual contact with other aircraft is reduced if aircraft operate in close proximity to clouds. One commenter stated that the proposals do not answer the need for clear radio failure procedures in Class B airspace areas. Another commenter stated that Class B airspace areas are actually divided into two types of Class B airspace: One in which a private pilot certificate is required and one in which, at a minimum, only a student pilot certificate is required.

This rulemaking reclassifies existing airspace areas with the equivalent recommended ICAO airspace area. It does not redesignate existing airspace areas. For example, the redesignation of a Class B airspace area (TCA) to a Class C airspace area (ARSA) is beyond the scope of this rulemaking. The FAA believes that the elimination of terminal areas designated as Class B airspace areas would create a substantial adverse impact on the safe and efficient control of air traffic in those high volume terminal areas. Class B airspace areas, like the TCAs that preceded them, provide more efficient control in terminal areas where there is a large volume of air traffic and where a high percentage of that traffic is large turbine-powered aircraft. Additionally, on July 25, 1991, the FAA revised FAA Order 7110.65, Air Traffic Control, by adopting specific separation standards for operations under VFR in existing TCAs. These standards require air traffic controllers to separate aircraft operating under VFR in existing TCAs from other aircraft operating under VFR and IFR.

As stated in NPRM No. 89–28 in response to NAR 1–7.2.9—Recommended VFR Minima, the FAA views the relaxation of the distance from cloud requirements for VFR operations as a modification that would enhance rather than reduce safety. Under the existing regulations, a pilot operating an aircraft under VFR in a TCA (Class B airspace) is provided with ATC services and is subject to ATC clearances and instructions. For the pilot operating under VFR to remain specific distances from clouds, the pilot must alter course or assigned heading/route, which is a disruption to traffic flow and could be a compromise to safety. The amendment will increase safety for pilots operating under VFR and ATC by permitting these pilots to remain clear of clouds in Class B airspace areas, but not requiring them to remain a specific distance from clouds. However, if an ATC instruction to a pilot operating an aircraft under VFR could place that aircraft in a cloud, FAR § 91.3, Responsibility and authority of the pilot in command, requires the pilot in command to be responsible for ensuring that the aircraft does not enter a cloud and any such ATC instruction may be refused.

Accordingly, as proposed, the FAA will reclassify TCAs as Class B airspace areas and amend the distance from cloud requirements for VFR operations to clear of clouds.

Even though ATC communication requirements for operations in Class B airspace areas are the same as those that exist in TCAs, the relaxation of the distance from cloud requirements will become effective with the new airspace classifications. This will ensure that all users are familiar with the amendment when it becomes effective.

The amendment to reclassify TCAs as Class B airspace areas does not modify the current operating rules for

communications. Lost communication requirements are addressed in paragraph 470, Two-way Radio Communications Failure, of the AIM and are not within the scope of the rulemaking.

The FAA accepted NAR 1–7.3.3—Pilot Requirements for Operations in a TCA, under the provisions of the existing requirements; hence, the reclassification of TCAs as Class B airspace areas meets existing regulations on minimum airman certificate levels. Section 61.95 of the FAR, which lists student pilot requirements for operations in a TCA (Class B airspace), is revised to meet the new airspace classification. Solo student pilot activity is, under both the existing regulations and this final rule, prohibited at certain airports.

Class C Airspace

Three comments were submitted on the reclassification of ARSAs as Class C airspace areas. None of the comments specifically support or oppose the reclassification. All of the comments, including one from EAA, addressed additional modifications.

Two commenters noted that the proposal for VFR operations in Class B airspace areas to remain clear of clouds could be applied to Class C airspace areas.

In its comment, EAA opposed any increase in the size of Class C airspace areas. Other recommendations by commenters included the need for clear radio failure procedures and the need for designated areas that do not require communications with ATC when the pilot desires to use an uncontrolled airport within Class C airspace areas.

As proposed, the FAA will reclassify ARSAs as Class C airspace areas. No other modifications to Class C airspace areas or changes in operating rules were proposed. An ARSA that currently operates on a part-time basis is classified as Class C part-time and Class D or Class E at other times.

Aircraft operating under VFR in Class C airspace areas operate under less stringent requirements than aircraft operating under VFR in Class B airspace areas and are not provided the same separation by ATC. Therefore, the relaxation of the VFR distance from cloud requirements in Class C airspace areas to remain clear of clouds would not be in accordance with safety precautions. As noted earlier, lost communication procedures are addressed in paragraph 470, Two-way Radio Communications Failure, of the AIM. Since Class C airspace areas often have a high number of aircraft that operate under IFR, a relaxation of existing communications requirements would not be in the interest of safety. Any modifications to the dimensions or operating requirements for Class C airspace areas are outside the scope of this rulemaking.

Class D Airspace

NPRM No. 89–28 proposed to reclassify control zones for airports with operating control towers and airport traffic areas, not associated with a TCA or an ARSA, as Class D airspace areas. In addition, NPRM No. 89–28 proposed to: (1) Raise the ceiling to up to, and including, 4,000 feet from the surface of the airport; (2) require aircraft in Class D airspace areas to establish two-way radio communications with ATC; and (3) convert the lateral unit of measurement from statute miles to nautical miles.

One hundred and forty comments concerning the proposal to establish the ceiling of the Class D airspace areas at 4,000 feet above the surface were submitted. All of the comments opposed the proposal.

Of the 83 comments regarding the proposal to require pilots who operate in Class D airspace areas to establish two-way radio communications with ATC, two supported the proposal and 80 opposed it. One comment neither supported nor opposed the proposals.

One hundred and forty-three comments related to the proposal to convert the lateral unit of measurement of Class D airspace areas from statute to nautical miles were submitted. Most interpreted the proposal to mean that the lateral size of the airspace areas would change from 5 statute miles to 5 nautical miles. (The FAA's intent in NPRM No. 89–28 is to convert statute miles as a unit of measurement to the equivalent in nautical miles.) Twelve comments supported and 131 comments opposed the proposal. Most of the commenters who specifically opposed the use of nautical miles instead of statute miles were opposed to a 5 nautical mile lateral measurement of Class D airspace areas.

The commenters who support the proposed conversion from statute to nautical miles or the proposed two-way radio communications requirements with ATC submitted suggestions and reasons for support. Some of these comments stated that the standardized use of nautical miles as opposed to statute miles could be expanded to weather reports, visibility requirements, and distance from cloud requirements above 10,000 feet MSL. ATCA stated that the proposal for two-way radio communications with ATC "erases a potentially dangerous practice and is long overdue." Another commenter suggested that a corridor could be provided in Class D airspace areas for operations at satellite airports without operating control towers.

The 140 commenters that opposed the proposed ceiling of 4,000 feet above the surface included AOPA, the Alaska Airmen's Association, the Arizona Pilots Association, EAA, the Ohio Department of Transportation, and SSA. These same organizations are represented in the 131 comments that opposed the proposed conversion from statute to nautical miles and the 80 comments that oppose the proposed two-way radio communications requirements with ATC.

Several comments, including one from EAA, were submitted on the effects of the proposed ceiling modification and communications requirements on operations under SFAR No. 51–1—Special Flight Rules in the Vicinity of Los Angeles International Airport. According to the comments, the proposal would raise the ceiling of the airport traffic areas at Santa Monica and Hawthorne Airports into the Special Flight Rules Area. The commenters also stated that the proposed two-way radio communication requirements with ATC may not allow aircraft, especially those with one radio, to listen to an advisory frequency.

Some commenters, including SSA, stated that airport traffic areas (Class D airspace) could be depicted on aeronautical charts. Several commenters, including AOPA, the Alaska Airmen's Association, EAA, and the Ohio Department of Transportation stated that the proposals would increase air traffic controller workload. Some comments, including one from AOPA, stated that the proposal would increase pilot workload or that no safety benefit exists for the proposed modifications.

Several commenters, including AOPA and EAA, requested that the ceiling of Class D airspace areas be lowered to 2,000 feet or 2,500 feet above the surface. The commenters stated that the lower altitudes are adequate for the arrival and departure of aircraft. Other commenters, including the Alaska Airmen's Association and SSA, recommended retaining the current ceiling of 3,000 feet above the surface.

Commenters stated that the proposals for modifying the size of airspace and for requiring two-way radio communications with ATC would be a burden to aircraft that fly at low altitudes, and that some aircraft would need to fly a minimum of 5,500 feet MSL as opposed to 3,500 feet MSL. Some commenters stated that the proposal would burden pilots of airplanes that do not have radios. One commenter noted

that pilots who fly older aircraft with no radios or navigational aids do not pose a threat to commercial aviation.

Several comments, including those submitted by the AOPA and the Alaska Airmen's Association, stated that the proposal for two-way radio communications with ATC would not permit aircraft to listen to the common traffic advisory frequency (CTAF) of satellite airports. Additional comments, including those submitted by the AOPA and EAA, noted that air traffic controllers in control towers cannot provide effective traffic advisories for satellite airports. Some commenters, including EAA and the Ohio Department of Transportation, stated that the proposed two-way radio communication requirements with ATC are not necessary because operations at satellite airports usually do not interfere with airports with operating control towers. Another commenter noted that a pilot who desires to use a satellite airport and needs to fly near an airport with an operating control tower would need to notify the local ATC facility.

Commenters, including the Arizona Pilots Association and EAA, recommended that the lateral unit of measurement of Class D airspace areas be designated at 4 nautical miles.

As proposed, control zones for airports with operating control towers and airport traffic areas that are not associated with a TCA or an ARSA are reclassified as Class D airspace areas. After considering public comment and re-examining technical criteria, the FAA has determined that: (1) The ceiling of a Class D airspace area (designated for an airport) will normally be designated at 2,500 feet above the surface of the airport converted to mean sea level (MSL), and rounded to the nearest 100 foot increment; (2) two-way radio communications with ATC will be required; and (3) the lateral dimensions will be expressed in nautical miles rounded up to the nearest tenth of a mile. The actual lateral and vertical dimensions will be determined on an individual basis using revised criteria in FAA Order 7400.2C, Procedures for Handling Airspace Matters. (More detail on the review of airspace appears under the title Implementation of Airspace Reclassification.)

Airspace at an airport with a part-time control tower is classified as a Class D airspace area when the control tower is in operation, and as a Class E airspace area when the control tower is not in operation.

The amendments do not affect operations under SFAR 51–1. The amendments to SFAR 51–1 replace the term "Terminal Control Area" with "Class B airspace area" and change the references to sections in Part 91 to the sections effective August 18, 1990. Any modifications to operations under an SFAR or Part 93, Special Air Traffic Rules and Airport Traffic Patterns, will be proposed under separate rulemaking actions.

Vertical Limit of Class D Airspace Areas

A goal of airspace reclassification is to enhance safety. The FAA is of the opinion that the existing airspace designations of an ARSA, which has a ceiling of "up to and including" 4,000 feet above the surface, and an airport traffic area, which has a ceiling of "up to, but not including," 3,000 feet above the surface, has caused confusion, which does not enhance safety. To promote uniformity, the FAA in NPRM No. 89–28 proposed that the ceiling of Class C, Class D, and Class E airspace areas that extend upward from the surface be established at "up to, and including" 4,000 feet above the surface. Many of the comments on this proposal were opposed to this modification. As previously stated, the FAA has determined that the ceiling of Class D airspace areas will normally be designated at up to, and including, 2,500 feet above the surface of the airport expressed in MSL. To further enhance uniformity, the ceiling of Class E airspace areas that extend upward from the surface normally will also have a ceiling established at up to, and including, 2,500 feet above the surface of the airport expressed in MSL. A ceiling of 2,500 feet above the surface will provide adequate vertical airspace to protect traffic patterns. However, the FAA emphasizes that the ceiling of a Class D or a Class E airspace area will reflect the conditions of the particular airspace area. For example, if local conditions warrant, the ceiling could be designated at more than 2,500 feet above the surface (e.g., 2,700 or 3,000 feet above the surface). Conversely, some airports with limited volume of nonturbine-powered aircraft may have a lower vertical limit.

The decision to use 2,500 feet above the surface is based on recent FAA analysis of vertical airspace necessary to protect traffic patterns and a review of public comment to lower the ceiling of an airport traffic area. The FAA's analysis demonstrates that the 2000-foot vertical limit is insufficient since it often does not protect traffic patterns for high performance aircraft.

Two-Way Radio Communications in and Lateral Dimensions of Class D Airspace Areas

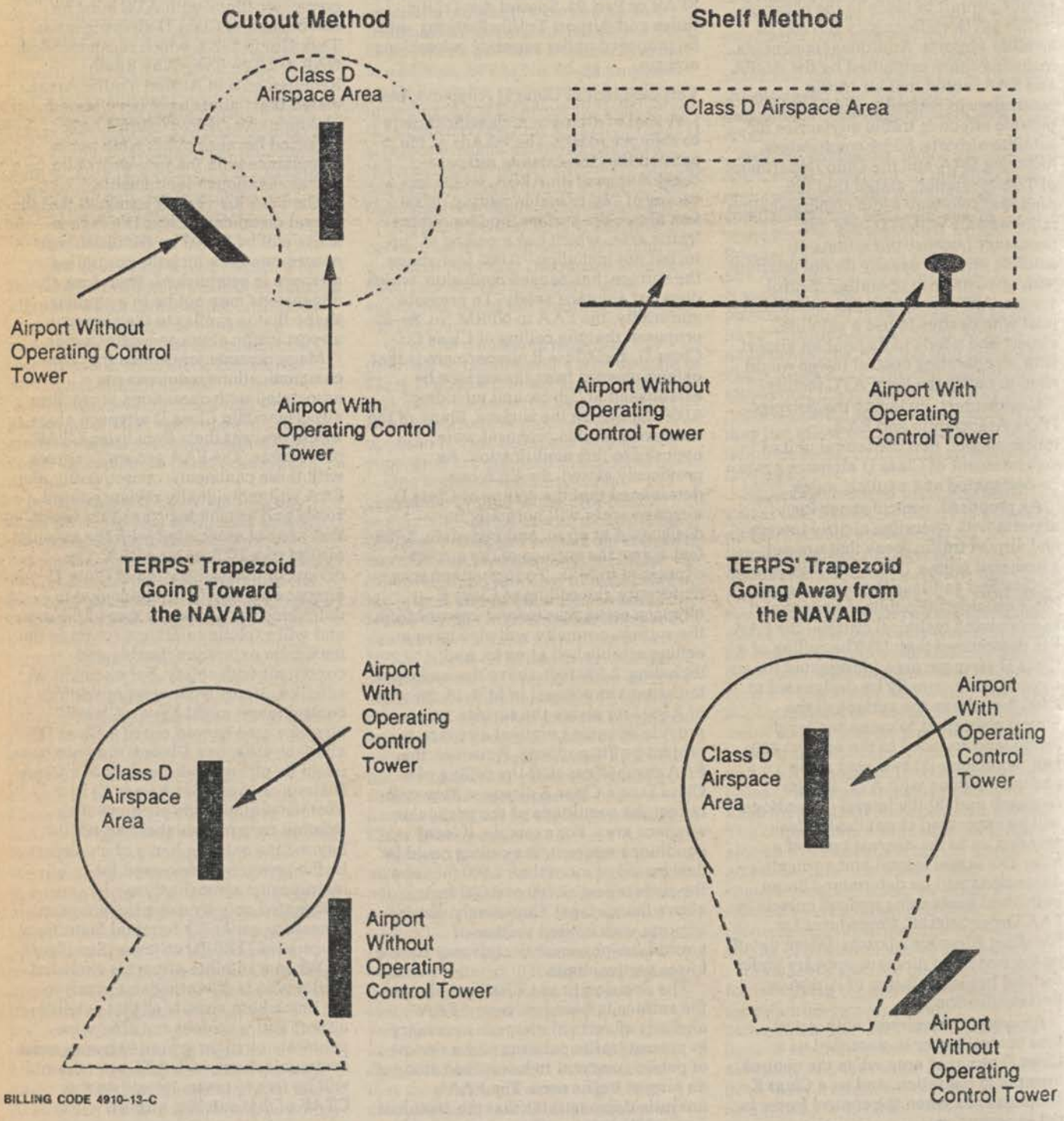
The FAA has determined that in order to meet safety standards, two-way radio communications with ATC must be established in Class D airspace areas. Task Group 1–2.3, which recommended NAR 1–2.3.2—Two-Way Radio Requirements in Airport Traffic Areas, stated that "pilots have been issued violations, or critical injuries have occurred because pilots were not in compliance with the two-way radio communications requirements."

The FAA also has determined that the lateral distance of Class D airspace areas will be based on the instrument procedures for which the controlled airspace is established. Therefore, the dimensions may not be in a circular shape that is similar to the current airport traffic areas or control zones.

Many commenters stated that the communications requirements associated with operations at satellite airports within Class D airspace areas would prevent them from using CTAF procedures. The FAA generally agrees with these comments; consequently, the FAA will individually review control zones and associated transition areas that are not associated with the primary airport of a TCA or an ARSA. The review of the designation of Class D airspace areas will be conducted to determine the necessary size of the area and will exclude satellite airports to the maximum extent practicable and consistent with safety. For example, a satellite airport without an operating control tower might have a Class E airspace area carved out of a Class D airspace area, or a Class E airspace area might be placed under a shelf of a Class D airspace area. (See Figure 1.) In another example, the portions of an existing control zone that extend beyond the existing limits of an airport traffic area (extension used for instrument approaches) may be designated only by using the airspace necessary under the terminal instrument procedures (TERPs) criteria. (See Figure 1.) When a satellite airport is excluded, a pilot who is operating an aircraft in the immediate vicinity of that satellite airport and who does not otherwise penetrate airspace where two-way radio communications with ATC are required will be free to communicate on the CTAF of that satellite airport.

BILLING CODE 4910-13-M

Figure 1. Examples of Satellite Airports Excluded from Class D Airspace Areas.



BILLING CODE 4910-13-C

The FAA will be flexible in the review of the airspace dimensions. However, pilots who operate at satellite airports that underlie the instrument arrival and departure path of the airport in Class D airspace areas may, in some instances, be required to establish two-way radio communications with ATC to comply with safety precautions.

Class E Airspace

NPRM No. 89–28 proposed to reclassify as Class E airspace areas as follows: All Federal airways, the Continental Control Area, control areas associated with jet routes outside the Continental Control Area, additional control areas, control area extensions, control zones for airports without operating control towers, transition areas, and area low routes. The five comments submitted on this proposal neither supported nor opposed the proposal, but offered suggestions.

One commenter noted that the current names are descriptions of how the airspace area is to be used (i.e., transition areas, airways) and that under the proposal, airways would still be necessary. The SSA recommended the continued use of the term "control zone" for airspace extending upward from the surface that is independent of Class B, Class C, or Class D airspace areas. They also recommended that control zones should extend to the floor of overlying controlled airspace. One commenter recommended that the floor of Class E airspace areas that are now 1,200 feet above ground level (AGL) be raised to 1,500 or 2,200 feet AGL and noted that the floor of Class E airspace areas should not be below the minimum en route IFR altitude (MEA) in mountainous regions.

The FAA will adopt the classification of Class E airspace areas as proposed. This classification will not eliminate the requirement for Federal airways, which are specified in part 71. However, this classification will eliminate the designation of control zones. Control zones for airports without operating control towers are classified as Class E airspace areas designated for an airport that extend upward from the surface.

The FAA believes that the reclassification of control zones for airports without operating control towers as Class E airspace areas will not cause confusion. As noted earlier, such airspace areas will be depicted on visual aeronautical charts by a segmented magenta line. Under existing regulations, a control zone usually has a 5-statute mile radius and ascends to the base of the Continental Control Area. The FAA's review process, using the revised criteria in FAA Order 7400.2C, will look at the dimensions of each control zone and associated transition areas. Each review will include a review of instrument approach procedures, as well as local terrain to determine the actual airspace needed to contain IFR operations.

The floor of Class E airspace areas, which do not extend upward from the surface, will remain the same as existing airspace areas (e.g., 700 feet AGL, 1,200 feet AGL, 1,500 feet AGL, 14,500 feet MSL). Any modifications to the floor of Class E airspace areas are beyond the scope of this rulemaking.

Class G Airspace

NPRM No. 89–28 proposed to reclassify airspace that is not otherwise designated as the Continental Control Area, a control area, a control zone, a terminal control area, a transition area, or SUA as Class G airspace areas. Of the six comments submitted, four comments opposed the proposal and two offered suggestions.

The four opposing comments, including EAA's comment, understood the Class G airspace areas to be airspace below 700 feet AGL.

The two comments that neither supported nor opposed the proposal included the comment from the ATA. The ATA recommended that Class G airspace areas be designated as Class F airspace areas.

The FAA has determined that all navigable airspace areas not otherwise designated as Class A, Class B, Class C, Class D, or Class E airspace areas or SUA are classified as Class G airspace areas. Since the proposal to replace the Continental Control Area with the U.S. control area in NPRM No. 88–2 was not adopted, the vertical limit of Class G airspace areas will vary (e.g., 700 feet AGL, 1,200 feet AGL, 1,500 feet AGL, 14,500 feet MSL). In addition, the flight visibility and distance from cloud requirements for operations under VFR proposed in NPRM No. 89–28 are modified to remain consistent with the existing requirements in §§ 91.155 and 103.23.

Class F airspace is omitted from the U.S. airspace classifications because this airspace, as adopted by ICAO, does not have a U.S. equivalent. Class G airspace, as adopted by ICAO, is the equivalent of U.S. uncontrolled airspace.

Additional Comments

Comments on issues affecting a specific class of airspace were also received. These comments with any modifications to the final rule are discussed below.

Some commenters, including AOPA, expressed apprehension that the FAA may reclassify airspace in an arbitrary manner. Other commenters, including EAA and SSA, believed the FAA implied in NPRM No. 89–28 that the person who is delegated airspace authority could allow any airspace designations considered appropriate.

In NPRM No. 89–28 and in this final rule, the FAA does not suggest that any new airspace designations could be specified without following rulemaking procedures where required. Further review of airspace areas will be proposed in future FAA rulemaking actions.

Three commenters, including the Alaska Airmen's Association and SSA, noted that NPRM No. 89–28 proposed to define controlled airspace in FAR § 1.1 as airspace in which "all aircraft may be subject to ATC" rather than airspace in which "some or all aircraft may be subject to ATC." According to one commenter, because aircraft operating under VFR are not always subject to ATC in controlled airspace, especially Class E airspace, the current definition is more accurate.

The proposed definition of controlled airspace is adopted in essence but it has been modified to correspond with ICAO's definition of a controlled airspace. Subsequent to the publication of NPRM No. 89–28, ICAO modified its definition of controlled airspace to read as follows: "Controlled airspace. An airspace of defined dimensions within which air traffic control service is provided to IFR flights and to VFR flights in accordance with the airspace classification. Note—Controlled airspace is a generic term which covers ATS (air traffic services) in airspace Classes A, B, C, D, and E." The proposed FAA definition in NPRM No. 89–28 read: "Controlled airspace means airspace designated as Class A, Class B, Class C, Class D, or Class E airspace in part 71 of this chapter and within which all aircraft may be subject to air traffic control."

While the commenter is essentially correct that all aircraft are not always subject to air traffic control, any aircraft may be subject to ATC if the pilot operates under IFR or if the pilot requests and receives air traffic services. The FAA believes that misunderstandings would be minimized with the adoption of the ICAO definition. The ICAO definition and the proposed definition are essentially synonymous; however, the FAA is confident the adoption of the ICAO definition is consistent with the objectives of airspace reclassification and that it is beneficial to have a

common international definition of controlled airspace.

Four commenters, including EAA and SSA, noted that NPRM No. 89–28 only permits Special VFR operations for the purposes of departing from or arriving at an airport. The commenters stated that such a restriction of Special VFR operations would affect pipeline patrol, aerial photography, law enforcement, agricultural, and other special types of operations. EAA also stated that the proposed limitation of 4,000 feet above the surface for Special VFR operations could prevent pilots from climbing to the top of a haze layer.

The FAA will continue to permit Special VFR operations for through flights as well as flights for arrival or departure. Because control zones will be eliminated under Airspace Reclassification, Special VFR operations are only permitted within the ceiling and lateral boundaries of the surface areas of the Class B, Class C, Class D, or Class E airspace designated for an airport. Because the proposal for a uniform ceiling for Class C, Class D, and Class E airspace areas at 4,000 feet above the surface is not adopted, the boundaries of the airspace area in which Special VFR operations are permitted will vary. For example, if a Class C airspace area has a ceiling designated at 4,500 feet MSL and a surface area designated within a 5-nautical mile radius from the airport, Special VFR operations are permitted within that 5-nautical mile radius up to and including 4,500 feet MSL.

One commenter, a flight instructor with a petition signed by additional flight instructors, stated that the language in the proposal on aerobatic flight is vague and could be interpreted to restrict aerobatic operations within existing transition areas and other less crowded airspace areas. The commenter was concerned that the proposed § 91.71(c) could affect spin training at flight schools.

Under this amendment, the term "control zone" will be eliminated. However, the FAA desires to continue restrictions that currently exist in the FAR on operations within control zones. These restrictions will now apply within the lateral boundaries of the surface areas of the Class B, Class C, Class D, or Class E airspace designated for an airport. For example, if a Class E airspace area is designated to extend upward from the surface with a 4.4-nautical mile radius from the airport and a ceiling of 2,600 feet MSL, aerobatic flight will not be permitted below 2,600 feet MSL within a 4.4-nautical mile radius of the airport.

Implementation of Airspace Reclassification

The implementation of the Airspace Reclassification final rule includes parallel reviews of certain existing airspace areas to meet the new airspace classifications. The outcome of the multi-phase review will be published in separate NPRMs. The reviews will focus on control zones, non-Federal control towers, transition areas, and offshore airspace. The FAA realizes that some of the reviews could be in areas with unique local conditions.

The FAA drafted changes to FAA Order 7400.2C, which focuses on existing control zones and transition areas. The changes to Order 7400.2C are considered independent of the Airspace Reclassification final rule, and involve the revised criteria to be used for the reviews. Because the changes to Order 7400.2C and the reviews occur before the effective date of the Airspace Reclassification final rule, the revised criteria are written in existing airspace terminology. Examples of the revised criteria include: (1) Converting the lateral unit of measurement from statute miles to nautical miles; (2) conforming existing control zones to be congruent with the lateral dimensions of the surface areas of existing TCAs or ARSAs; (3) redesignating control zones to contain intended operations (not necessarily in a circular configuration); (4) redesignating the vertical limit of control zones from the surface of the earth to a specified altitude (but not to the base of the Continental Control Area); (5) establishing a policy to exclude satellite airports from control zones to the maximum extent practicable, consistent with instrument procedures and safety; and (6) replacing control zone departure extensions with transition areas.

The FAA anticipates that many control zones and associated transition areas would require minor modification. For example, a control zone could be integrated with the associated TCA or ARSA (Class B or Class C airspace area) or a control zone could become either a Class D airspace area or a Class E airspace area that extends upward from the surface.

The reviews will include control zones where a significant change in the current airspace structure is expected. For example, a control zone that extends beyond the perimeter of the associated TCA or ARSA and could require modification of the associated TCA or ARSA (Class B or Class C airspace area). The reviews will also include transition areas not associated with control zones and offshore airspace. Proposed changes that result from these reviews will be promulgated using normal rulemaking procedures.

The reviews could also result in the expansion of controlled airspace. These actions could affect airspace areas associated with non-Federal control towers. Any expansion of controlled airspace will be proposed in future NPRMs.

All necessary changes to the airspace structures are scheduled to be completed by September 16, 1993, the effective date of the Airspace Reclassification final rule.

Changes to the NPRM

This final rule includes several nonsubstantive editorial changes made to NPRM No. 89–28. Changes are also included in this final rule to certain FAR sections that were not included in NPRM No. 89–28 but require changes in terminology to be consistent with the amendments. Three additional subparts in part 93 are deleted because the rules will not be necessary under airspace reclassification. The sections and subparts, with an explanation of the changes made to them, follow.

SFAR 51–1

The reference to "Terminal Control Area (TCA)" in section 1 is replaced with "Class B airspace area." The reference to § 91.105(a) in section 2(a) is replaced with § 91.155(a). The reference to § 91.24(b) in section 2(b) is replaced with § 91.215(b). The phrase "meet the equipment requirements" in section 2(b) is replaced with "be equipped as." The reference to § 91.90(a) and § 91.90 in section 3 is replaced with § 91.131(a) and § 91.131.

SFAR 60

The references to "terminal control area" and "airport radar service area" in section 3a are replaced with "Class B airspace area" and "Class C airspace area." The phrase "terminal and en route airspace" in section 3a is replaced with "class of controlled airspace."

SFAR 62

The two references to "terminal control area" in section 1(a) are replaced with "Class B airspace area." The references to the "Tri-Area TCA" in section 2(24) and (25) are replaced with "Tri-Area Class B airspace area."

§ 45.22(a)(3)(i)

The phrase "the designated airport control zone of the takeoff airport, or within 5 miles of that airport if it has no designated control zone" is replaced with "the lateral boundaries of the

surface areas of Class B, Class C, Class D, or Class E airspace designated for the takeoff airport, or within 4.4 nautical miles of that airport if it is within Class G airspace."

§ 61.95

All references to "terminal control area" in the title and paragraphs (a), (a)(1), (a)(2), (a)(3), and (b) are replaced with "Class B airspace" or "Class B airspace area."

§ 61.193(b)(4)

Both references to a "terminal control area" are replaced with "Class B airspace area."

§ 61.195(d)(3)

Both references to a "terminal control area" are replaced with "Class B airspace area."

Part 75

This part is removed and reserved with all sections being transferred to a new subpart M in existing Part 71.

§ 91.126

This section is established to include the existing requirements in § 91.127 on operations on or in the vicinity of an airport without an operating control tower.

§ 91.905

The references to §§ 91.127, 91.129, 91.130, 91.131, and 91.135 are replaced with the titles to become effective September 16, 1993, and a reference is added to § 91.126.

§ 93.1(b)

The reference to § 93.113, which is to be deleted as of September 16, 1993, is deleted.

Subpart N, part 93

This subpart on the airport traffic area at the Sabre U.S. Army Heliport (Tennessee) is removed and reserved. On September 16, 1993, this airspace will become a Class D airspace area.

Subpart O, part 93

This subpart on the Navy airport traffic area at Jacksonville, Florida, is removed and reserved. On September 16, 1993, this airspace will become three separate but adjoining Class D airspace areas.

Subpart R, part 93

This subpart on the Special Air Traffic Rules at El Toro California, is removed and reserved. On September 16, 1993, this airspace will become a part of the El Toro Class C airspace area.

§ 135.205(b)

The reference to "uncontrolled airspace" is replaced with "Class G airspace." The reference to "control zones" is replaced with "within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport."

§ 139.323(a)

The reference to "terminal control area" is replaced with "Class B airspace area."

§ 171.9(e)(1) and (e)(2)

All references to "air traffic control areas" are replaced with "controlled airspace."

§ 171.29(d)(1) and (d)(2)

All references to "air traffic control areas" are replaced with "controlled airspace."

§ 171.159(e)(1) and (e)(2)

Both references to "air traffic control areas" are replaced with "controlled airspace." The reference to "air traffic control zones or areas" is replaced with "controlled airspace."

§ 171.209(d)

Both references to "air traffic control areas" are replaced with "controlled airspace." The reference to "air traffic control zones or areas" is replaced with "controlled airspace."

§ 171.323(i)

The reference to "air traffic control areas" is replaced with "controlled airspace." The reference to "air traffic control zones or areas" is replaced with "controlled airspace."

Obsolete Dates

Obsolete dates have been removed from §§ 91.215 (b)(2), (b)(4), and (b)(5)(ii). Section 91.215(b)(5)(i)(A) is obsolete and is deleted. Section 91.215(b)(5)(i)(B) is incorporated into existing § 91.215(b)(5)(i).

Regulatory Evaluation Summary

This section summarizes the full regulatory evaluation prepared by the FAA that provides more detailed estimates of the economic consequences of this final rule regulatory action. This summary and the full evaluation quantify, to the extent practicable, estimated costs to the private sector, consumers, Federal, State and local governments, as well as anticipated benefits.

Executive Order 12291, dated February 17, 1981, directs Federal agencies to promulgate new regulations or modify existing regulations only if potential benefits to society for each regulatory change outweigh potential costs. The order also requires the preparation of a Regulatory Impact Analysis of all major rules except those responding to emergency situations or other narrowly defined exigencies. A major rule is one that is likely to result in an annual effect on the economy of $100 million or more, a major increase in consumer costs, a significant adverse effect on competition, or one that is highly controversial.

The FAA has determined that this rule is not major as defined in the executive order. Therefore, a full regulatory analysis, that includes the identification and evaluation of cost reducing alternatives to the final rule, has not been prepared. Instead, the agency has prepared a more concise document termed a regulatory evaluation that analyzes only this rule without identifying alternatives. In addition to a summary of the regulatory evaluation, this section also contains a final regulatory flexibility determination required by the 1980 Regulatory Flexibility Act (Pub. L. 96–354) and an International Trade Impact Assessment. If the reader desires more detailed economic information than this summary contains, then he/she should consult the full regulatory evaluation contained in the docket.

Benefit-Cost Analysis

The regulatory evaluation examines the costs and benefits of this final rule to reclassify U.S. airspace. This rule is intended to simplify airspace designations, achieve international commonality of airspace designations, standardize equipment requirements and associate appropriate pilot certification requirements as well as certain other requirements associated with each proposed airspace designation. These changes are based primarily on recommendations from a National Airspace Review (NAR) task group and will ultimately allow for increased safety and efficiency in the U.S. airspace and air traffic control system.

Costs

The FAA estimates the total incremental cost that will accrue from the implementation of this final rule to be $1.9 million (discounted, in 1990 dollars). Virtually all cost, which is expected to be incurred by the FAA, will accrue from revisions to aeronautical charts, re-education of the pilot community, and revision of air traffic controller training courses. Each one of these factors is briefly discussed below:

1. Revisions to Aeronautical Charts

A significant cost impact associated with this rule will result from the requirement to change aeronautical charts. These modifications will be incorporated during the regular updating and printing of the charts. Therefore, all costs associated with printing aeronautical charts are assumed to be normal costs of doing business. However, because of dimension and symbol changes that will be needed, the plates used to print the charts will need to be changed, and this will affect most of the aeronautical charts printed.

The total cost of revisions to all charts is estimated by the National Ocean Service based on the summation of the costs of revising each class of the airspace. The total discounted cost is estimated to be $1.2 million.

2. Revision of Air Traffic Training Courses

Manuals, textbooks, and other training materials used to educate FAA controllers will need to be updated to reflect the airspace reclassification. According to the FAA Aeronautical Center in Oklahoma City, lesson plans, visual aids, handouts, laboratory exercises, and tests will need to be revised.

The cost of these revisions is determined by multiplying the total revision time by the hourly cost of the course manager making the changes. The course managers are level GS–14 (step 5) employees with an average loaded annual salary of $72,000. Assuming 2,080 hours per year, their average loaded hourly salary is $35. The cost of the course changes is estimated to be $43,000 (discounted). An additional cost of $10,000 (discounted) will accrue as the result of a one-week seminar and associated travel. This seminar will be necessary to educate course managers about the airspace reclassification. The total cost that will accrue from this factor is estimated to be $43,000 (discounted).

3. Re-education of the Pilot Community

Pilots who are presently certificated to operate in the U.S. airspace will need to become familiar with the airspace reclassification as the result of this rule. This task will be accomplished through a variety of publications, videotapes, and pilot meetings.

The FAA is considering the production of a videotape that will be provided as a public service to industry associations, such as AOPA, ALPA, and NBAA, to inform them of the airspace reclassification. This videotape could be shown at various association meetings to help re-educate the pilot community. The FAA's Office of Public Affairs, estimates that the film will be 20 to 25 minutes long and could be produced at a cost of $75,000 (discounted).

The FAA is also considering the publication of an advisory circular (AC) which will document the new airspace classifications. The AC will be mailed to each registered pilot. It is estimated that one man-week at a level GS–14 (Step 5) will be required to draft the AC and obtain approval in the sponsoring organization, and one GS–14 man-week will be required to obtain FAA approval of the AC. The cost associated with 2 man-weeks at a level GS–14 needed to prepare the AC is estimated to be $2,500 (discounted). This cost was estimated using the average loaded hourly salary of a level GS–14 employee which is $35.

After the AC is approved, it will be mailed to approximately 761,000 registered pilots. Assuming that the AC will be 10 pages long and the cost of reproduction is $0.05 per page, the cost of reproduction will be $346,000 (discounted). Assuming that the shipping and handling charge associated with each copy is $0.29, the cost of shipping and handling is $201,000 (discounted). The cost impact that will result for re-educating the pilot community was estimated by summing the cost of the videotape and the AC, described in the preceding paragraphs. This estimated cost impact is $625,000 (discounted).

Benefits

This final rule is expected to generate benefits in the form of enhanced safety and operational efficiency to the aviation community. These benefits are briefly described, in qualitative terms, below:

1. Increased Safety Due to Better Understanding and Simplification

The FAA believes that the simplified classification in this rule will reduce airspace complexity and thereby enhance safety. This airspace reclassification mirrors the new ICAO airspace designations, except there will not be a U.S. Class F airspace.

This rule also will increase safety in the U.S. since foreign pilots operating aircraft in U.S. airspace will be familiar with the airspace designations and classification system.

Another simplification which is expected to help increase airspace safety is the change that will correlate the class of controlled airspace currently termed a control zone to the airspace of the surrounding area. Currently, several types of airspace are designated around an airport, which makes it difficult for pilots and controllers to determine how the areas are classified and which requirements apply. After the reclassification, the terminology will be more explanatory.

The conversion of statute mile designations to nautical mile designations is intended to further simplify operations. Since the instruments on-board the aircraft are calibrated in nautical miles and aviation charts have representations in nautical miles, this change will eliminate the need for pilots to convert between nautical and statute miles. This simplification will help pilots and controllers to be better able to understand the airspace designations in part 71.

2. Reduced Minimum Distance from Cloud Requirement

This airspace reclassification will designate TCAs as Class B airspace areas. The VFR minimum distance from clouds requirement in this airspace will also change. Currently this distance is 500 feet below, 1,000 feet above, and 2,000 feet horizontal. In Class B airspace, the rule will require that the minimum distance from clouds be "clear of clouds." This change will afford VFR traffic increased opportunities to fly in Class B airspace in more types of weather than they currently have in a TCA. Furthermore, there will be reduced requests for deviation from ATC instruction to maintain cloud clearance. This action will not threaten safety since all aircraft operating in Class B airspace are provided with the appropriate separation.

3. Operation Of Ultralight Vehicles

This rule incorporates NAR task group 1–7.2 recommendations and changes part 103 to correspond to the new airspace designations found in part 71. There will be no decrease in safety because there is no change in the type of airspace in which ultralights are permitted to fly or operate.

Conclusion

Despite the fact that benefits are not quantifiable in monetary terms, the FAA, nonetheless, concludes that the benefits of this rule are expected to outweigh its expected costs.

International Trade Impact Assessment

Since this rule will not affect airspace outside the United States for which the United States is responsible, it is not expected to impose any new operating requirement in that airspace. As such, it will have no affect on the sale of foreign aviation products or services in the United States, nor will it affect the sale

of U. S. products or services in foreign countries.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The RFA requires agencies to review rules which may have "a significant cost impact on a substantial number of small entities." The small entities which could be potentially affected by the implementation of this notice are pilot schools.

Training materials used in the courses offered by the pilot schools will have to be modified to reflect the changes of the airspace reclassification. However, pilot schools will not incur any cost impact since the documents they use will be updated as a normal course of business. Thus, there will be no cost impact to those pilot schools classified as small entities. Therefore, this rule will not have a significant cost impact on a substantial number of small entities.

Federalism Implications

The amendments in this final rule will not have substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that these amendments will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96-511), there are no requirements for information collection associated with this rule.

Conclusion

For reasons discussed in the preamble, and based on the findings in the Regulatory Evaluation Determination and the International Trade Impact Analysis, the FAA has determined that these amendments do not qualify as a major rule under Executive Order 12291. In addition, the FAA certifies that these amendments will not have a significant economic effect on a substantial number of small business entities under the criteria of the Regulatory Flexibility Act. These amendments are considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A regulatory evaluation of these amendments, including a Regulatory Flexibility Determination and Trade Impact Analysis, has been placed in its entirety in the regulatory docket. A copy may be obtained by contacting the person identified under "**FOR FURTHER INFORMATION CONTACT.**"

Cross Reference

To identify where existing regulations for part 75 are relocated in existing part 71, the following cross reference lists are provided:

Cross Reference Table

Old section	New section
75.1	71.601.
75.11	71.603.
75.13	71.605.
75.17	Deleted.
75.100	71.607.
75.400	71.609.

New Section	Old Section
71.601	75.1.
71.603	75.11.
71.605	75.13.
71.607	75.100.
71.609	75.400.

To identify where existing regulations for part 71 are relocated in the rule to be effective September 16, 1993, or if the regulations will be relocated in FAA Order 7400.9, the following cross reference lists are provided:

Cross Reference Table

Old section	New section or FAA order 7400.9
71.1	71.1.
71.3	71.73.
71.5	71.75.
71.6	71.77.
71.7	Deleted.
71.9	71.71.
71.11	Deleted.
71.12	71.41.
71.13	71.71.
71.14	71.51.
71.15	71.31.
71.17	71.5.
71.19	71.7.
71.101	Subpart E of FAA Order 7400.9.
71.103	Subpart E of FAA Order 7400.9.
71.105	Subpart E of FAA Order 7400.9.
71.107	Subpart E of FAA Order 7400.9
71.109	Subpart E of FAA Order 7400.9
71.121	71.79.
71.123	Subpart E of FAA Order 7400.9
71.125	Subpart E of FAA Order 7400.9
71.127	Subpart E of FAA Order 7400.9.
71.151	Subpart E of FAA Order 7400.9.
71.161	71.71 and Subpart E of FAA Order 7400.9.
71.163	71.71 and Subpart E of FAA Order 7400.9.
71.165	Subpart E of FAA Order 7400.9.
71.171	Subpart D or E of FAA Order 7400.9
71.181	Subpart E of FAA Order 7400.9
71.193	71.33.
71.201	71.901.
71.203	Subpart H of FAA Order 7400.9.
71.207	Subpart H of FAA Order 7400.9.
71.209	Subpart H of FAA Order 7400.9.
71.211	Subpart H of FAA Order 7400.9.
71.213	Subpart H of FAA Order 7400.9.
71.215	Subpart H of FAA Order 7400.9.
71.301	Subpart E of FAA Order 7400.9.
71.401	Subpart B of FAA Order 7400.9.
71.501	Subpart C of FAA Order 7400.9.
71.601	Deleted
71.603	Subpart A of FAA Order 7400.9.
71.605	Subpart A of FAA Order 7400.9.
71.607	Subpart A of FAA Order 7400.9.
71.609	Subpart A of FAA Order 7400.9.

New Section	Old Section
71.1	71.1.
71.5	71.17.
71.7	71.19.
71.9	New.
71.31	71.15.
71.33	71.193.
71.41	71.12.
71.51	71.14.
71.61	New.
71.71	71.9, 71.13, 71.161, 71.163.
71.73	71.3.
71.75	71.5.
71.77	71.6.
71.79	71.121.
71.901	71.201.

FAA Order 7400.9	Old Section
Subpart A	71.603.
Subpart A	71.605.
Subpart A	71.607.
Subpart A	71.609.
Subpart B	71.401.
Subpart C	71.501.
Subpart D or Subpart E	71.171.
Subpart E	71.101.
Subpart E	71.103.
Subpart E	71.105.
Subpart E	71.107.
Subpart E	71.109.
Subpart E	71.123.
Subpart E	71.125.
Subpart E	71.127.
Subpart E	71.151.
Subpart E	71.161.
Subpart E	71.163.
Subpart E	71.165.

FAA Order 7400.9	Old Section
Subpart E	71.181.
Subpart E	71.301.
Subpart H	71.203.
Subpart H	71.207.
Subpart H	71.209.
Subpart H	71.211.
Subpart H	71.213.
Subpart H	71.215.

List of Subjects

14 CFR Part 1

Air safety, Air transportation, Aviation safety, Safety, Transportation.

14 CFR Part 11

Administrative practice and procedure, Reporting and recordkeeping requirements.

14 CFR Part 45

Air safety, Air transportation, Aviation safety, Safety, Transportation.

14 CFR Part 61

Air safety, Air transportation, Airmen, Aviation safety, Pilots, Students, Safety, Transportation.

14 CFR Part 65

Air safety, Air transportation, Airmen, Airports, Aviation safety, Reporting and recordkeeping requirements, Safety.

14 CFR Part 71

Airspace, Airways, Incorporation by reference.

14 CFR Part 75

Airspace, Airways.

14 CFR Part 91

Air safety, Air traffic control, Air transportation, Airmen, Airports, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 93

Special air traffic rules.

14 CFR Part 101

Air safety, Air transportation, Aircraft, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 103

Air safety, Air transportation, Aircraft, Aviation safety, Recreation and recreation areas.

14 CFR Part 105

Air safety, Air transportation, Aircraft, Airports, Airspace, Aviation safety, Recreation and recreation areas, Reporting and recordkeeping requirements.

14 CFR Part 121

Air carrier, Air safety, Air traffic control, Air transportation, Aircraft, Airmen, Aviation safety, Charter flights, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 127

Air carrier, Air safety, Air transportation, Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 135

Air carrier, Air safety, Air traffic control, Air transportation, Aircraft, Airmen, Airspace, Aviation Safety.

14 CFR Part 137

Air safety, Agriculture, Aircraft, Aviation safety.

14 CFR Part 139

Air carrier, Air safety, Air transportation, Aircraft, Airports, Aviation safety.

14 CFR Part 171

Air traffic control, Aircraft, Airports, Airspace, Navigation, Reporting and recordkeeping requirements.

The Rule

In consideration of the foregoing, the Federal Aviation Administration amends SFAR 51–1, SFAR 60, SFAR 62, parts 1, 11, 45, 61, 65, 71, 75, 91, 93, 101, 103, 105, 121, 127, 135, 137, 139, and 171 of Federal Aviation Regulations (14 CFR parts 1, 11, 45, 61, 65, 71, 75, 91, 93, 101, 103, 105, 121, 127, 135, 137, 139, and 171) as follows:

PART 91—[AMENDED]

Part 91 is amended as follows:

SFAR No. 51–1—SPECIAL FLIGHT RULES IN THE VICINITY OF LOS ANGELES INTERNATIONAL AIRPORT

1. The authority citation for Special Federal Aviation Regulation No. 51–1 is revised to read as follows:

Authority: 49 U.S.C. app. 1303, 1348, 1354(a), 1421, and 1422; 49 U.S.C. 106(g).

2. Special Federal Aviation Regulation No. 51–1 is amended by revising section 1 introductory text, paragraphs 2(a) and 2(b) of section 2, and section 3 to read as follows:

Section 1. Applicability: This rule establishes a special operating area for persons operating aircraft under visual flight rules (VFR) in the following airspace of the Los Angeles Class B airspace area designated as the Los Angeles Special Flight Rules Area: * * *

Section 2. * * *

a. The flight must be conducted under VFR and only when operation may be conducted in compliance with § 91.155(a).

b. The aircraft must be equipped as specified in FAR 91.215(b) replying on Code 1201 prior to entering and while operating in this area.

* * * * *

Section 3. Notwithstanding the provisions of § 91.131(a), an air traffic control authorization is not required in the Los Angeles Special Flight Rules Area for operations in compliance with section 2 of this SFAR. All other provisions of § 91.131 apply to operate in the Special Flight Rules Area.

SFAR NO. 60—AIR TRAFFIC CONTROL SYSTEM EMERGENCY OPERATION

3. The authority citation for SFAR No. 60 is revised to read as follows:

Authority: 49 U.S.C. app. 1301(7), 1303, 1344, 1348, 1352 through 1355, 1401, 1421 through 1431, 1471, 1472, 1502, 1510, 1522, and 2121 through 2125; articles 12, 29, 31, and 32(a) of the Convention on International Civil Aviation (61 stat. 1180); 42 U.S.C. 4321 *et seq.*; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp., p. 902; 49 U.S.C. 106(g).

4. Special Federal Aviation Regulation No. 60 is amended by revising paragraph (a) of section 3 to read as follows:

* * * * *

3. * * *

(a) Restrict, prohibit, or permit VFR and/or IFR operations at any airport, Class B airspace area, Class C airspace area, or other class of controlled airspace.

* * * * *

SFAR NO. 62—SUSPENSION OF CERTAIN AIRCRAFT OPERATIONS FROM THE TRANSPONDER WITH AUTOMATIC PRESSURE ALTITUDE REPORTING CAPABILITY REQUIREMENT

5. The authority citation for SFAR No. 62 is revised to read as follows:

Authority: 49 U.S.C. app. 1301(7), 1303, 1344, 1348, 1352 through 1355, 1401, 1421 through 1431, 1471, 1472, 1502, 1510, 1522, and 2121 through 2125; articles 12, 29, 31, and 32(a) of the Convention on International Civil Aviation (61 stat. 1180); 42 U.S.C. 4321 *et seq.*; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp., p. 902; 49 U.S.C. 106(g).

6. Special Federal Aviation Regulation No. 62 is amended by revising paragraph (a) of section 1 and introductory text of both paragraphs (24) and (25) of section 2 to read as follows:

Section 1. * * *

(a) The airspace within 30 nautical miles of a Class B airspace area primary airport, from the surface upward to 10,000 feet MSL, excluding the airspace designated as a Class B airspace area is referred to as the Mode C veil.

* * * * *

Section 2. * * *

* * * * *

(24) Effective until the establishment of the Washington Tri-Area Class B airspace area or December 30, 1993, whichever occurs first:

* * *

(25) Effective upon the establishment of the Washington Tri-Area Class B airspace area:

* * *

* * * * *

PART 1—DEFINITIONS AND ABBREVIATIONS

7. The authority citation for part 1 is revised to read as follows:

Authority: 49 U.S.C. app. 1347, 1348, 1354(a), 1357(d)(2), 1372, 1421 through 1430, 1432, 1442, 1443, 1472, 1510, 1522, 1652(e), 1655(c), 1657(f); 49 U.S.C. 106(g).

8. Section 1.1 is amended by removing the definition of "airport traffic area," revising the definition of "controlled airspace," and adding the definitions of "Special VFR conditions" and "Special VFR operations" in alphabetical order to read as follows:

§ 1.1 General definitions.

* * * * *

Controlled airspace means an airspace of defined dimensions within which air traffic control service is provided to IFR flights and to VFR flights in accordance with the airspace classification.

Note—Controlled airspace is a generic term that covers Class A, Class B, Class C, Class D, and Class E airspace.

* * * * *

Special VFR conditions mean meteorological conditions that are less than those required for basic VFR flight in controlled airspace and in which some aircraft are permitted flight under visual flight rules.

Special VFR operations means aircraft operating in accordance with clearances within controlled airspace in meteorological conditions less than the basic VFR weather minima. Such operations must be requested by the pilot and approved by ATC.

* * * * *

PART 11—GENERAL RULEMAKING PROCEDURES

9. The authority citation for part 11 is revised to read as follows:

Authority: 49 U.S.C. app. 1341(a), 1343(d), 1348, 1354(a), 1401 through 1405, 1421 through 1431, 1481, 1502; 49 U.S.C. 106(g).

10. Section 11.61 is amended by revising paragraphs (a)(1) and (c) to read as follows:

§ 11.61 Scope.

(a) * * *

(1) Designations of controlled airspace under part 71 of this chapter;

* * * * *

(c) For the purposes of this subpart, "Director" means the Executive Director of System Operations, the Associate Administrator for Air Traffic or the Director, Air Traffic Rules and Procedures Service, or any person to whom the Director has delegated authority in the matter concerned.

* * * * *

PART 45—IDENTIFICATION AND REGISTRATION MARKING

11. The authority citation for part 45 is revised to read as follows:

Authority: 49 U.S.C. app. 1348, 1354, 1401, 1402, 1421, 1423, 1522, 1655(c).

12. Section 45.22 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 45.22 Exhibition, antique, and other aircraft: Special rules.

(a) * * *

(3) * * *

(i) It is operated with the prior approval of the Flight Standards District Office, in the case of a flight within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for the takeoff airport, or within 4.4 nautical miles of that airport if it is within Class G airspace; or

* * * * *

PART 61—CERTIFICATION: PILOTS AND FLIGHT INSTRUCTORS

13. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355, 1421, 1422, and 1427; 49 U.S.C. 106(g).

14. Section 61.95, paragraph (a) and (b) introductory text are revised to read as follows:

§ 61.95 Operations in Class B airspace and at airports located within Class B airspace.

(a) A student pilot may not operate an aircraft on a solo flight in Class B airspace unless—

(1) The pilot has received both ground and flight instruction from an authorized instructor on that Class B airspace area and the flight instruction was received in the specific Class B airspace area for which solo flight is authorized;

(2) The logbook of that pilot has been endorsed within the preceding 90 days for conducting solo flight in that Class B airspace area by the instructor who gave the flight training; and

(3) The logbook endorsement specifies that the pilot has received the required ground and flight instruction and has been found competent to conduct solo flight in that specific Class B airspace area.

(b) Pursuant to § 91.131(b), a student pilot may not operate an aircraft on a solo flight to, from, or at an airport located within Class B airspace unless—

* * * * *

15. Section 61.193 is amended by revising paragraph (b)(4) to read as follows:

§ 61.193 Flight instructor authorizations.

* * * * *

(b) * * *

(4) In accordance with § 61.95, the logbook of a student pilot the flight instructor has instructed authorizing solo flights in a Class B airspace area or at an airport within a Class B airspace area;

* * * * *

16. Section 61.195 is amended by revising paragraph (d)(3) to read as follows:

§ 61.195 Flight instructor limitations.

* * * * *

(d) * * *

(3) For solo flight in a Class B airspace area or at an airport within a Class B airspace area unless the flight instructor has given that student ground and flight instruction and has found that student prepared and competent to conduct the operations authorized.

* * * * *

PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

17. The authority citation for part 65 is revised to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1355, 1421, 1422, and 1427; 49 U.S.C. 106(g).

18. Section 65.37 is amended by revising paragraphs (f) introductory text and (f)(2) to read as follows:

§ 65.37 Skill requirements: Operating positions.

* * * * *

(f) Each of the following procedures that is applicable to that operating position and is required by the person performing the examination:

* * * * *

(2) The terrain features, visual checkpoints, and obstructions within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for the airport.

* * * * *

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, REPORTING POINTS, JET ROUTES, AND AREA HIGH ROUTES

19. The heading for part 71 is revised as set forth above.

19A. The authority citation for part 71 is revised to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

20. Section 71.1 is revised to read as follows:

§ 71.1 Applicability.

The complete listing for all jet routes and area high routes can be found in FAA Order 7400.7, Compilation of Regulations, which was last published as of April 30, 1991, and effective November 1, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The approval to incorporate by reference FAA Order 7400.7 is effective as of December 17, 1991 through September 15, 1993. Copies of this order may be obtained from the Document Inspection Facility, APA–220, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, (202) 267–3484. Copies may be inspected in Docket Number 24456 at the Federal Aviation Administration, Office of the Chief Counsel, AGC–10, room 915G, 800 Independence Avenue, SW., Washington, DC 20591 weekdays between 8:30 a.m. and 5 p.m. or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC. This section is effective as of December 17, 1991, through September 15, 1993.

* * * * *

21. Section 71.11 is revised to read as follows:

§ 71.11 Control zone.

The control zones listed in subpart F of FAA Order 7400.7 (incorporated by reference, see § 71.1) consist of controlled airspace which, unless otherwise specified, extends upward from the surface of the earth and terminates at the base of the continental control area. Unless otherwise specified, control zones that do not underlie the continental control area have no upper limit. A control zone may include one or more airports and is normally a circular area with extensions as necessary to include instrument approach paths.

22. Section 71.19 is revised to read as follows:

§ 71.19 Bearings; radials; miles.

All bearings and radials in this part are true and are applied from point of origin and all mileages in this part are stated as nautical miles.

23. Subpart M consisting of § 71.601–71.609, is added to read as follows:

Subpart M—Jet Routes and Area High Routes

Sec.
71.601 Applicability.
71.603 Jet routes.
71.605 Area Routes above 18,000 feet MSL.
71.607 Jet route descriptions.
71.609 Area high route descriptions

§ 71.601 Applicability.

The routes described in § 71.607 between high altitude navigational aids or intersections of their signals, are designated as jet routes along which aircraft may be operated between 18,000 feet MSL and flight level 450. The routes described in § 71.609 are designated as area high routes.

§ 71.603 Jet routes.

Each jet route designated in § 71.607 consists of a direct course for navigating between 18,000 feet MSL and flight level 450, inclusive, between the navigational aids and intersections specified for that route.

§ 71.605 Area routes above 18,000 feet MSL.

Each area route designated in § 71.609 consists of a direct course for navigating aircraft at altitudes between 18,000 feet MSL and flight level 450, inclusive, between the waypoints specified for that route.

§ 71.607 Jet route descriptions.

Each jet route description can be found in part 75 of FAA Order 7400.7 (incorporated by reference, see § 71.1).

§ 71.609 Area high route descriptions.

Each area route description can be found in part 75 of FAA Order 7400.7 (incorporated by reference, see § 71.1).

24. Part 71 is revised to read as follows: (Effective September 16, 1993)

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

Subpart A—General; Class A Airspace

Sec.
71.1 Airspace classification.
71.3 [Reserved]
71.5 Reporting points.
71.7 Bearings, radials, and mileages.
71.9 Overlapping airspace designations.
71.31 Class A airspace.
71.33 Class A airspace areas.

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Subpart H—Reporting Points

Sec.
71.901 Applicability.

Authority: 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. app. 106(g) 14 CFR 11.69.

Subpart A—General; Class A Airspace

§ 71.1 Airspace classification.

The complete listing of these airspace designations can be found in FAA Order 7400.9, Airspace Reclassification, which is effective September 16, 1993. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The approval to incorporate by reference FAA Order 7400.9 is effective as of September 16, 1993, through September 15, 1994. Copies of this order may be obtained from the Document Inspection Facility, APA–220, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591 (202) 267–3484. Copies may be inspected in Docket No. 24456 at the Federal Aviation Administration, Office of the Chief Counsel, AGC–10, room 915G, 800 Independence Avenue, SW., Washington, DC 20591 weekdays between 8:30 a.m. and 5 p.m. or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, D.C.

(a) The airspace assignments described in this subpart are designated as Class A airspace areas.

(b) The airspace assignments described in subpart B are designated as Class B airspace areas.

(c) The airspace assignments described in subpart C are designated as Class C airspace areas.

(d) The airspace assignments described in subpart D are designated as Class D airspace areas.

(e) The airspace assignments described in subpart E are designated as Class E airspace areas.

(f) Airspace not assigned in subpart A, B, C, D, E, or H of this part is uncontrolled airspace and is designated as Class G airspace.

§ 71.3 [Reserved]

§ 71.5 Reporting points.

The reporting points listed in subpart H of FAA Order 7400.9 (incorporated by reference, see § 71.1) consist of geographic locations at which the position of an aircraft must be reported in accordance with part 91 of this chapter.

§ 71.7 Bearings, radials, and mileages.

All bearings and radials in this part are true and are applied from point of origin and all mileages in this part are stated as nautical miles.

§ 71.9 Overlapping airspace designations.

(a) When overlapping airspace designations apply to the same airspace, the operating rules associated with the more restrictive airspace designation apply.

(b) For the purpose of this section—

(1) Class A airspace is more restrictive than Class B, Class C, Class D, Class E, or Class G airspace;

(2) Class B airspace is more restrictive than Class C, Class D, Class E, or Class G airspace;

(3) Class C airspace is more restrictive than Class D, Class E, or Class G airspace;

(4) Class D airspace is more restrictive than Class E or Class G airspace; and

(5) Class E is more restrictive than Class G airspace.

§ 71.31 Class A airspace.

The airspace descriptions contained in § 71.33 and the routes contained in subpart A of FAA Order 7400.9 (incorporated by reference, see § 71.1) are designated as Class A airspace within which all pilots and aircraft are subject to the rating requirements, operating rules, and equipment requirements of Part 91 of this chapter.

§ 71.33 Class A airspace areas.

(a) That airspace of the United States, including that airspace overlying the waters within 12 nautical miles of the coast of the 48 contiguous States, from 18,000 feet MSL to and including FL600 excluding the states of Alaska and Hawaii, Santa Barbara Island, Farallon Island, and the airspace south of latitude 25°04'00" North.

(b) That airspace of the State of Alaska, including that airspace overlying the waters within 12 nautical miles of the coast, from 18,000 feet MSL to and including FL600 but not including the airspace less than 1,500 feet above the surface of the earth and the Alaska Peninsula west of longitude 160°00'00" West.

Subpart B—Class B Airspace

§ 71.41 Class B airspace.

The Class B airspace areas listed in subpart B of FAA Order 7400.9 (incorporated by reference, see § 71.1) consist of specified airspace within which all aircraft operators are subject to the minimum pilot qualification requirements, operating rules, and aircraft equipment requirements of part 91 of this chapter. Each Class B airspace area designated for an airport in subpart B of FAA Order 7400.9 (incorporated by reference, see § 71.1) contains at least one primary airport around which the airspace is designated.

Subpart C Class C Airspace

§ 71.51 Class C airspace.

The Class C airspace areas listed in subpart C of FAA Order 7400.9 (incorporated by reference, see § 71.1) consist of specified airspace within which all aircraft operators are subject to operating rules and equipment requirements specified in part 91 of this chapter. Each Class C airspace area designated for an airport in subpart C of FAA Order 7400.9 (incorporated by reference, see §71.1) contains at least one primary airport around which the airspace is designated

Subpart D—Class D Airspace

§ 71.61 Class D airspace.

The Class D airspace areas listed in subpart D of FAA Order 7400.9 (incorporated by reference, see § 71.1) consist of specified airspace within which all aircraft operators are subject to operating rules and equipment requirements specified in part 91 of this chapter. Each Class D airspace area designated for an airport in subpart D of FAA Order 7400.9 (incorporated by reference, see § 71.1) contains at least one primary airport around which the airspace is designated.

Subpart E—Class E Airspace

71.71 Class E airspace.

Class E Airspace consists of:

(a) The airspace of the United States, including that airspace overlying the waters within 12 nautical miles of the coast of the 48 contiguous states and Alaska, extending upward from 14,500 feet MSL up to, but not including 18,000 feet MSL, and excluding—

(1) The Alaska peninsula west of longitude 160°00'00"W.;

(2) The airspace below 1,500 feet above the surface of the earth; and

(3) Prohibited and restricted areas, other than restricted areas listed in subpart E of FAA Order 7400.9 (incorporated by reference, see §71.1).

(b) The airspace areas designated for an airport in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1) within which all aircraft operators are subject to the operating rules specified in part 91 of this chapter.

(c) The airspace areas listed as domestic airspace areas in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1) which extend upward from 700 feet or more above the surface of the earth when designated in conjunction with an airport for which an approved instrument approach procedure has been prescribed, or from 1,200 feet or more above the surface of the earth when designated in conjunction with segments of airways or routes. When such areas are designated in conjunction with airways or routes, the extent of such designation has the lateral extent identical to that of a Federal airway and extends upward from 1,200 feet or higher unless otherwise specified.

(d) The Federal airways and area low routes described and listed in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1).

(e) The airspace areas listed as offshore airspace areas in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1) which are designated in international airspace within areas of domestic radio navigational signal or ATC radar coverage, and within which domestic ATC procedures are applied. When designated in conjunction with a route, the extent of such designation is as follows:

(1) Unless otherwise specified, the airspace centered on each jet route segment listed in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1) has a vertical extent identical to that of a jet route and a lateral extent identical to that of a Federal airway. Unless otherwise specified, the place names appearing in the descriptions indicate VOR or VORTAC facilities identified by those names.

(2) Unless otherwise specified, each airspace area has a lateral extent identical to that of a Federal airway and extends upward from 1,200 feet above the surface of the earth.

§ 71.73 Classification of Federal airways.

Federal airways are classified as follows:

(a) Colored Federal airways:
(1) Green Federal airways.
(2) Amber Federal airways.
(3) Red Federal airways.
(4) Blue Federal airways.
(b) VOR Federal airways.

§ 71.75 Extent of Federal airways.

(a) Each Federal airway is based on a center line that extends from one navigational aid or intersection to another navigational aid (or through several navigational aids or intersections) specified for that airway.

(b) Unless otherwise specified:

(1) Each Federal airway includes the airspace within parallel boundary lines 4 miles each side of the center line. Where an airway changes direction, it includes that airspace enclosed by extending the boundary lines of the airway segments until they meet.

(2) Where the changeover point for an airway segment is more than 51 miles from either of the navigational aids defining that segment, and—

(i) The changeover point is midway between the navigational aids, the airway includes the airspace between lines diverging at angles of 4.5° from the center line at each navigational aid and extending until they intersect opposite the changeover point; or

(ii) The changeover point is not midway between the navigational aids, the airway includes the airspace between lines diverging at angles of 4.5° from the center line at the navigational aid more distant from the changeover point, and extending until they intersect with the bisector of the angle of the center lines at the changeover point; and between lines connecting these points of intersection and the navigational aid nearer to the changeover point.

(3) Where an airway terminates at a point or intersection more than 51 miles from the closest associated navigational aid, it includes the additional airspace within lines diverging at angles of 4.5° from the center line extending from the associated navigational aid to a line perpendicular to the center line at the termination point.

(4) Where an airway terminates, it includes the airspace within a circle centered at the specified navigational aid or intersection having a diameter equal to the airway width at that point. However, an airway does not extend into an oceanic control area.

(c) Unless otherwise specified—

(1) Each Federal airway includes that airspace extending upward from 1,200 feet above the surface of the earth to, but not including, 18,000 feet MSL, except that Federal airways for Hawaii have no upper limits. Variations of the lower limits of an airway are expressed in digits representing hundreds of feet above the surface or MSL and, unless otherwise specified, apply to the segment of an airway between adjoining navigational aids or intersections; and

(2) The airspace of a Federal airway, within the lateral limits of a Class E airspace area with a lower floor, has a floor coincident with the floor of that area.

(d) A Federal airway does not include the airspace of a prohibited area.

§ 71.77 Extent of area low routes.

(a) Each area low route is based on a center line that extends from one waypoint to another waypoint (or through several waypoints) specified for that area low route. An area low route does not include the airspace of a prohibited area. All mileages specified in connection with area low routes are nautical miles.

(b) Unless otherwise specified in subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1), the following apply:

(1) Except as provided in paragraph (2) of this section, each area low route includes, and is limited to, that airspace within parallel boundary lines 4 or more miles on each side of the route center line as described in the middle column of the following table, plus that additional airspace outside those parallel lines and within lines drawn outward from those parallel lines at angles of 3.25°, beginning at the distance from the tangent point specified in the right-hand column of the following table:

Miles from reference facility point to tangent point	Miles from center line to parallel lines	Miles from tangent along parallel line to vertices of 3.25° angles
Less than 17	4	51
17 to, but not including 27	4	50
27 to, but not including 33	4	49
33 to, but not including 38	4	48
38 to, but not including 43	4	47
43 to, but not including 47	4	46
47 to, but not including 51	4	45
51 to, but not including 55	4	44
55 to, but not including 58	4	43
58 to, but not including 61	4	42
61 to, but not including 63	4	41
63 to, but not including 66	4	40
66 to, but not including 68	4	39
68 to, but not including 70	4	38
70 to, but not including 72	4	37
72 to, but not including 74	4	36
74 to, but not including 76	4	35
76 to, but not including 78	4	34
78 to, but not including 79	4	33
79 to, but not including 81	4	32
81 to, but not including 83	4	31
83 to, but not including 84	4	30
84 to, but not including 86	4	29
86 to, but not including 87	4	28
87 to, but not including 88	4	27
88 to, but not including 89	4	26
89 to, but not including 91	4	25
91 to, but not including 92	4	24

Miles from reference facility point to tangent point	Miles from center line to parallel lines	Miles from tangent along parallel line to vertices of 3.25° angles
92 to, but not including 93	4	23
93 to, but not including 94	4	22
94 to, but not including 95	4	21
95 to, but not including 96	4	19
96 to, but not including 97	4	18
97 to, but not including 98	4	17
98 to, but not including 99	4	15
99 to, but not including 100	4	13
100 to, but not including 101	4	11
101 to, but not including 102	4	8
102 to, but not including 105	4	0 (i.e., at tangent point).
105 to, but not including 115	4.25	0 (i.e., at tangent point).
115 to, but not including 125	4.50	0 (i.e., at tangent point).
125 to, but not including 135	4.75	0 (i.e., at tangent point).
135 to, but not including 145	5.00	0 (i.e., at tangent point).
145 to, but not including 150	5.25	0 (i.e., at tangent point).

(2) Each area low route, whose center line is at least 2 miles, and not more than 3 miles from the reference facility, includes, in addition to the airspace specified in subparagraph (1) of this paragraph, that airspace on the reference facility side of the center line that is within lines connecting the point that is 4.9 miles from the tangent point on a perpendicular line from the center line through the reference facility, thence to the edges of the boundary lines described in paragraph (b)(1) of this section, intersecting those boundary lines at angles of 5.15°.

(3) Where an area low route changes direction, it includes that airspace enclosed by extending the boundary lines of the route segments until they meet.

(4) Where the widths of adjoining route segments are unequal, the following apply:

(i) If the tangent point of the narrower segment is on the route center line, the width of the narrower segment includes that additional airspace within lines from the lateral extremity of the wider segment where the route segments join, thence toward the tangent point of the narrower route segment, until intersecting the boundary of the narrower segment.

(ii) If the tangent point of the narrower segment is on the route center line extended, the width of the narrower segment includes that additional airspace within lines from the lateral extremity of the wider segment where the route segments join, thence toward the tangent point until reaching the point where the narrower segment terminates or changes direction, or until intersecting the boundary of the narrower segment.

(5) Where an area low route terminates, it includes that airspace within a circle whose center is the terminating waypoint, and whose diameter is equal to the route segment width at that waypoint, except that an area low route does not extend into an oceanic control area.

(6) Each area low route includes that airspace extending upward from 1,200 feet above the surface of the earth to, but not including, 18,000 feet MSL, except that area low routes for Hawaii have no upper limits. Variations of the lower limits of an area low route are expressed in digits representing hundreds of feet above the surface or MSL and, unless otherwise specified, apply to the route segment between adjoining waypoints used in the description of the route.

(7) The airspace of an area low route within the lateral limits of a 700- or 1,200-foot above the surface Class E airspace area has a floor coincident with the floor of that area.

§ 71.79 Designation of VOR Federal airways.

Unless otherwise specified the place names appearing in the descriptions of airspace areas in Subpart E of FAA Order 7400.9 (incorporated by reference, see § 71.1) designated as VOR Federal airways indicate VOR or VORTAC navigational facilities identified by those names.

Subpart F—[Reserved]

Subpart G—[Reserved]

Subpart H—Reporting Points

§ 71.901 Applicability.

Unless otherwise designated:

(a) Each reporting point listed in Subpart H of FAA Order 7400.9 (incorporated by reference, see § 71.1) applies to all directions of flight. In any case where a geographic location is designated as a reporting point for less than all airways passing through that point, or for a particular direction of flight along an airway only, it is so indicated by including the airways or direction of flight in the designation of geographical location.

(b) Place names appearing in the reporting point descriptions indicate VOR or VORTAC facilities identified by those names.

PART 75—ESTABLISHMENT OF JET ROUTES AND AREA HIGH ROUTES

25. The part 75 is removed and reserved.

PART 91—GENERAL OPERATING AND FLIGHT RULES

26. The authority citation for part 91 is revised to read as follows:

Authority: 49 U.S.C. app. 1301(7), 1303, 1344, 1348, 1352 through 1355, 1401, 1421 through 1431, 1471, 1472, 1502, 1510, 1522, and 2121 through 2125; articles 12, 29, 31, and 32(a) of the Convention on International Civil Aviation (61 stat. 1180); 42 U.S.C. 4321 *et seq.*; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp., p. 902; 49 U.S.C. 106(g).

27. Section 91.117 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 91.117 Aircraft speed.

(a) Unless otherwise authorized by the Administrator (or by ATC in the case of operations in Class A or Class B airspace), no person may operate an aircraft below 10,000 feet MSL at an indicated airspeed of more than 250 knots (288 mph).

(b) Unless otherwise authorized or required by ATC, no person may operate an aircraft at or below 2,500 feet above the surface within 4 nautical miles of the primary airport of a Class B, Class C, or Class D airspace area at an indicated airspeed of more than 200 knots (230 mph.).

(c) No person may operate an aircraft in the airspace underlying a Class B airspace area designated for an airport or in a VFR corridor designated through such a Class B airspace area, at an indicated airspeed of more than 200 knots (230 mph).

* * * * *

28. Section 91.123 is amended by revising paragraph (a) to read as follows:

§ 91.123 Compliance with ATC clearances and instructions.

(a) When an ATC clearance has been obtained, a pilot in command may not deviate from that clearance, except in an emergency, unless that pilot obtains an amended clearance. However, except in Class A airspace, this paragraph does not prohibit that pilot from canceling an IFR flight plan if the operation is being conducted in VFR weather conditions. When a pilot is uncertain of an ATC clearance, that pilot must immediately request clarification from ATC.

* * * * *

29. Section 91.126 is added to read as follows:

§ 91.126 Operating on or in the vicinity of an airport in Class G airspace.

(a) *General.* Unless otherwise authorized or required, each person operating an aircraft on or in the vicinity of an airport in a Class G airspace area must comply with the requirements of this section.

(b) *Direction of turns.* When approaching to land at an airport in a Class G airspace area—

(1) Each pilot of an airplane must make all turns of that airplane to the left unless the airport displays approved light signals or visual markings indicating that turns should be made to the right, in which case the pilot must make all turns to the right; and

(2) Each pilot of a helicopter must avoid the flow of fixed-wing aircraft.

(c) *Flap settings.* Except when necessary for training or certification, the pilot in command of a civil turbojet-powered aircraft must use, as a final flap setting, the minimum certificated landing flap setting set forth in the approved performance information in the Airplane Flight Manual for the applicable conditions. However, each pilot in command has the final authority and responsibility for the safe operation of the pilot's airplane, and may use a different flap setting for that airplane if the pilot determines that it is necessary in the interest of safety.

30. Section 91.127 is revised to read as follows:

§ 91.127 Operating on or in the vicinity of an airport in Class E airspace.

(a) Unless otherwise required by part 93 of this chapter or unless otherwise authorized or required by the ATC facility having jurisdiction over the Class E airspace area, each person operating an aircraft on or in the vicinity of an airport in a Class E airspace area must comply with the requirements of § 91.126.

(b) *Departures.* Each pilot of an aircraft must comply with any traffic patterns established for that airport in part 93 of this chapter.

31. Section 91.129 is revised to read as follows:

§ 91.129 Operations in Class D airspace.

(a) *General.* Unless otherwise authorized or required by the ATC facility having jurisdiction over the Class D airspace area, each person operating an aircraft in Class D airspace must comply with the applicable provisions of this section. In addition, each person must comply with §§ 91.126 and 91.127. For the purpose of this section, the primary airport is the airport for which the Class D airspace area is designated. A satellite airport is any other airport within the Class D airspace area.

(b) *Deviations.* An operator may deviate from any provision of this section under the provisions of an ATC authorization issued by the ATC facility having jurisdiction over the airspace concerned. ATC may authorize a deviation on a continuing basis or for an individual flight, as appropriate.

(c) *Communications.* Each person operating an aircraft in Class D airspace must meet the following two-way radio communications requirements:

(1) *Arrival or through flight.* Each person must establish two-way radio communications with the ATC facility (including foreign ATC in the case of foreign airspace designated in the United States) providing air traffic services prior to entering that airspace and thereafter maintain those communications while within that airspace.

(2) *Departing flight.* Each person—

(i) From the primary airport or satellite airport with an operating control tower must establish and maintain two-way radio communications with the control tower, and thereafter as instructed by ATC while operating in the Class D airspace area; or

(ii) From a satellite airport without an operating control tower, must establish and maintain two-way radio communications with the ATC facility having jurisdiction over the Class D airspace area as soon as practicable after departing.

(d) *Communications failure.* Each person who operates an aircraft in a Class D airspace area must maintain two-way radio communications with the ATC facility having jurisdiction over that area.

(1) If the aircraft radio fails in flight under IFR, the pilot must comply with § 91.185 of the part.

(2) If the aircraft radio fails in flight under VFR, the pilot in command may operate that aircraft and land if—

(i) Weather conditions are at or above basic VFR weather minimums;

(ii) Visual contact with the tower is maintained; and

(iii) A clearance to land is received.

(e) *Minimum altitudes.* Each pilot of a large or turbine-powered airplane must—

(1) Unless otherwise required by the applicable distance from cloud criteria, enter the traffic pattern at an altitude of at least 1,500 feet above the elevation of the airport and maintain at least 1,500 feet until further descent is required for a safe landing;

(2) When approaching to land on a runway served by an instrument landing system (ILS), if the airplane is ILS-equipped, fly that airplane at an altitude at or above the glide slope between the outer marker (or point of interception of glide slope, if compliance with the applicable distance from clouds criteria requires interception closer in) and the middle marker; and

(3) When operating an airplane approaching to land on a runway served by a visual approach slope indicator, maintain an altitude at or above the glide slope until a lower altitude is necessary for safe landing.

Paragraphs (e)(2) and (e)(3) of this section do not prohibit normal bracketing maneuvers above or below the glide slope that are conducted for the purpose of remaining on the glide slope.

(f) *Approaches.* Except when conducting a circling approach under Part 97 of this chapter or unless otherwise required by ATC, each pilot must—

(1) Circle the airport to the left, if operating an airplane; or

(2) Avoid the flow of fixed-wing aircraft, if operating a helicopter.

(g) *Departures.* No person may operate an aircraft departing from an airport except in compliance with the following:

(1) Each pilot must comply with any departure procedures established for that airport by the FAA.

(2) Unless otherwise required by the prescribed departure procedure for that airport or the applicable distance from clouds criteria, each pilot of a turbine-powered airplane and each pilot of a large airplane must climb to an altitude of 1,500 feet above the surface as rapidly as practicable.

(h) *Noise abatement.* Where a formal runway use program has been established by the FAA, each pilot of a large or turbine-powered airplane assigned a noise abatement runway by ATC must use that runway. However, consistent with the final authority of the pilot in command concerning the safe operation of the aircraft as prescribed in § 91.3(a), ATC may assign a different runway if requested by the pilot in the interest of safety.

(i) *Takeoff, landing, taxi clearance.* No person may, at any airport with an operating control tower, operate an aircraft on a runway or taxiway, or take off or land an aircraft, unless an appropriate clearance is received from ATC. A clearance to "taxi to" the takeoff runway assigned to the aircraft is not a clearance to cross that assigned takeoff runway, or to taxi on that runway at any point, but is a clearance to cross other runways that intersect the taxi route to that assigned takeoff runway. A clearance to "taxi to" any point other than an assigned takeoff runway is clearance to cross all runways that intersect the taxi route to that point.

32. Section 91.130 is revised to read as follow:

§ 91.130 Operations in Class C airspace.

(a) *General.* Each aircraft operation in Class C airspace must be conducted in compliance with this section and § 91.129. For the purpose of this section, the primary airport is the airport for which the Class C airspace area is designated. A satellite airport is any other airport within the Class C airspace area.

(b) *Traffic patterns.* No person may take off or land an aircraft at a satellite airport within a Class C airspace area except in compliance with FAA arrival and departure traffic patterns.

(c) *Communications.* Each person operating an aircraft in Class C airspace must meet the following two-way radio communications requirements:

(1) *Arrival or through flight.* Each person must establish two-way radio communications with the ATC facility (including foreign ATC in the case of foreign airspace designated in the United States) providing air traffic services prior to entering that airspace and thereafter maintain those communications while within that airspace.

(2) *Departing flight.* Each person—

(i) From the primary airport or satellite airport with an operating control tower must establish and maintain two-way radio communications with the control tower, and thereafter as instructed by ATC while operating in the Class C airspace area; or

(ii) From a satellite airport without an operating control tower, must establish and maintain two-way radio communications with the ATC facility having jurisdiction over the Class C airspace area as soon as practicable after departing.

(d) *Equipment requirements.* Unless otherwise authorized by the ATC having jurisdiction over the Class C airspace area, no person may operate an aircraft within a Class C airspace area designated for an airport unless that aircraft is equipped with the applicable equipment specified in § 91.215.

33. Section 91.131 is revised to read as follows:

§ 91.131 Operations in Class B airspace.

(a) *Operating rules.* No person may operate an aircraft within a Class B airspace area except in compliance with § 91.129 and the following rules:

(1) The operator must receive an ATC clearance from the ATC facility having jurisdiction for that area before operating an aircraft in that area.

(2) Unless otherwise authorized by ATC, each person operating a large turbine engine-powered airplane to or from a primary airport for which a Class B airspace area is designated must operate at or above the designated floors of the Class B airspace area while within the lateral limits of that area.

(3) Any person conducting pilot training operations at an airport within a Class B airspace area must comply with any procedures established by ATC for such operations in that area.

(b) *Pilot requirements.*

(1) No person may take off or land a civil aircraft at an airport within a Class B airspace area or operate a civil aircraft within a Class B airspace area unless—

(i) The pilot in command holds at least a private pilot certificate; or

(ii) The aircraft is operated by a student pilot or recreational pilot who seeks private pilot certification and has met the requirements of § 61.95 of this chapter.

(2) Notwithstanding the provisions of paragraph (b)(1)(ii) of this section, no person may take off or land a civil aircraft at those airports listed in section 4 of appendix D of this part unless the pilot in command holds at least a private pilot certificate.

(c) *Communications and navigation equipment requirements.* Unless otherwise authorized by ATC, no person may operate an aircraft within a Class B airspace area unless that aircraft is equipped with—

(1) *For IFR operation.* An operable VOR or TACAN receiver; and

(2) *For all operations.* An operable two-way radio capable of communications with ATC on appropriate frequencies for that Class B airspace area.

(d) *Transponder requirements.* No person may operate an aircraft in a Class B airspace area unless the aircraft is equipped with the applicable operating transponder and automatic altitude reporting equipment specified in paragraph (a) of § 91.215, except as provided in paragraph (d) of that section.

34. Section 91.135 is revised to read as follows:

§ 91.135 Operations in Class A airspace.

Except as provided in paragraph (d) of this section, each person operating an aircraft in Class A airspace must conduct that operation under instrument flight rules (IFR) and in compliance with the following:

(a) *Clearance.* Operations may be conducted only under an ATC clearance received prior to entering the airspace.

(b) *Communications.* Unless otherwise authorized by ATC, each aircraft operating in Class A airspace must be equipped with a two-way radio capable of communicating with ATC on a frequency assigned by ATC. Each pilot must maintain two-way radio communications with ATC while operating in Class A airspace.

(c) *Transponder requirement.* Unless otherwise authorized by ATC, no person may operate an aircraft within Class A airspace unless that aircraft is equipped with the applicable equipment specified in § 91.215.

(d) *ATC authorizations.* An operator may deviate from any provision of this section under the provisions of an ATC authorization issued by the ATC facility having jurisdiction of the airspace concerned. In the case of an inoperative transponder, ATC may immediately approve an operation within a Class A airspace area allowing flight to continue, if desired, to the airport of ultimate destination, including any intermediate stops, or to proceed to a place where suitable repairs can be made, or both. Requests for deviation from any provision of this section must be submitted in writing, at least 4 days

before the proposed operation. ATC may authorize a deviation on a continuing basis or for an individual flight.

35. Section 91.155 is revised to read as follows:

§ 91.155 Basic VFR weather minimums.

(a) Except as provided in paragraph (b) of this section and § 91.157, no person may operate an aircraft under VFR when the flight visibility is less, or at a distance from clouds that is less, than that prescribed for the corresponding altitude and class of airspace in the following table:

Airspace	Flight visibility	Distance from clouds
Class A	Not Applicable	Not Applicable.
Class B	3 statute miles	Clear of Clouds.
Class C	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.
Class D	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.
Class E:		
Less than 10,000 feet MSL	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal
At or above 10,000 feet MSL	5 statute miles	1,000 feet below. 1,000 feet above. 1 statute mile horizontal.
Class G:		
1,200 feet or less above the surface (regardless of MSL altitude).		
Day, except as provided in § 91.155(b).	1 statute mile	Clear of clouds.
Night, except as provided in § 91.155(b).	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.
More than 1,200 feet above the surface but less than 10,000 feet MSL		
Day	1 statute mile	500 feet below. 1,000 feet above. 2,000 feet horizontal.
Night	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.
More than 1,200 feet above the surface and at or above 10,000 feet MSL.	5 statute miles	1,000 feet below. 1,000 feet above. 1 statute mile horizontal.

(b) *Class G Airspace.* Notwithstanding the provisions of paragraph (a) of this section, the following operations may be conducted in Class G airspace below 1,200 feet above the surface:

(1) *Helicopter.* A helicopter may be operated clear of clouds if operated at a speed that allows the pilot adequate opportunity to see any air traffic or obstruction in time to avoid a collision.

(2) *Airplane.* When the visibility is less than 3 statute miles but not less than 1 statute mile during night hours, an airplane may be operated clear of clouds if operated in an airport traffic pattern within one-half mile of the runway.

(c) Except as provided in § 91.157, no person may operate an aircraft, under VFR, within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport when the ceiling is less than 1,000 feet.

(d) Except as provided in § 91.157 of this part, no person may take off or land an aircraft, or enter the traffic pattern of an airport, under VFR, within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport—

(1) Unless ground visibility at that airport is at least 3 statute miles; or

(2) If ground visibility is not reported at that airport, unless flight visibility during landing or takeoff, or while operating in the traffic pattern is at least 3 statute miles.

(e) For the purpose of this section, an aircraft operating at the base altitude of a Class E airspace area is considered to be within the airspace directly below that area.

36. Section 91.157 is revised to read as follows:

§ 91.157 Special VFR weather minimums.

Except as provided in appendix D, section 3 of this part, the following special weather minimums and requirements apply to operations conducted to or from an airport in controlled airspace:

(a) Operations may be conducted only under an ATC clearance—

(1) Within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport; and

(2) Except for helicopters, between sunrise and sunset (or in Alaska, when the sun is 6° or more above the horizon) unless—

(i) That person meets the applicable requirements for instrument flight under part 61 of this chapter; and

(ii) The aircraft is equipped as required in § 91.205(d).

(b) Operations may only be conducted clear of clouds.

(c) Except for helicopters, operations may be conducted only when flight visibility is at least 1 statute mile.

(d) No person may take off or land an aircraft (other than a helicopter)—

(1) Unless ground visibility is at least 1 statute mile; or

(2) If ground visibility is not reported, unless flight visibility during landing and takeoff is at least 1 statute mile.

37. Section 91.215 is amended by revising paragraphs (b) and (d) to read as follows:

§ 91.215 ATC transponder and altitude reporting equipment and use.

* * * * *

(b) *All airspace.* Unless otherwise authorized or directed by ATC, no person may operate an aircraft in the airspace described in paragraphs (b)(1) through (b)(5) of this section, unless that aircraft is equipped with an operable coded radar beacon transponder having either Mode 3/A 4096 code capability, replying to Mode 3/A interrogations with the code specified by ATC, or a Mode S capability, replying to Mode 3/A interrogations with the code specified by ATC and intermode and Mode S interrogations in accordance with the applicable provisions specified in TSO C–112, and that aircraft is equipped with automatic pressure altitude reporting equipment having a Mode C capability that automatically replies to Mode C interrogations by transmitting pressure altitude information in 100-foot increments. This requirement applies—

(1) *All aircraft.* In Class A, Class B, and Class C airspace areas;

(2) *All aircraft.* In all airspace within 30 nautical miles of an airport listed in appendix D, section 1 of this part from the surface upward to 10,000 feet MSL;

(3) Notwithstanding paragraph (b)(2) of this section, any aircraft which was not originally certificated with an engine-driven electrical system or which has not subsequently been certified with such a system installed, balloon or glider may conduct operations in the airspace within 30 nautical miles of an airport listed in appendix D, section 1 of this part provided such operations are conducted—

(i) Outside any Class A, Class B, or Class C airspace area; and

(ii) Below the altitude of the ceiling of a Class B or Class C airspace area designated for an airport or 10,000 feet MSL, whichever is lower; and

(4) All aircraft in all airspace above the ceiling and within the lateral boundaries of a Class B or Class C airspace area designated for an airport upward to 10,000 feet MSL; and

(5) All aircraft except any aircraft which was not originally certificated with an engine-driven electrical system or which has not subsequently been certified with such a system installed, balloon, or glider——

(i) In all airspace of the 48 contiguous states and the District of Columbia at and above 10,000 feet MSL, excluding the airspace at and below 2,500 feet above the surface; and

(ii) In the airspace from the surface to 10,000 feet MSL within a 10-nautical-mile radius of any airport listed in appendix D, section 2 of this part, excluding the airspace below 1,200 feet outside of the lateral boundaries of the surface area of the airspace designated for that airport.

* * * * *

(d) *ATC authorized deviations.* Requests for ATC authorized deviations must be made to the ATC facility having jurisdiction over the concerned airspace within the time periods specified as follows:

(1) For operation of an aircraft with an operating transponder but without operating automatic pressure altitude reporting equipment having a Mode C capability, the request may be made at any time.

(2) For operation of an aircraft with an inoperative transponder to the airport of ultimate destination, including any intermediate stops, or to proceed to a place where suitable repairs can be made or both, the request may be made at any time.

(3) For operation of an aircraft that is not equipped with a transponder, the request must be made at least one hour before the proposed operation.

38. Section 91.303 is amended by revising paragraphs (c), (d), and (e) and by adding paragraph (f) to read as follows:

§ 91.303 Aerobatic flight.

* * * * *

(c) Within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport;

(d) Within 4 nautical miles of the center line of any Federal airway;

(e) Below an altitude of 1,500 feet above the surface; or

(f) When flight visibility is less than 3 statute miles.

* * * * *

39. Section 91.309 is amended by revising paragraph (a)(4) to read as follows:

§ 91.309 Towing: Gliders.

(a) * * *

(4) Before conducting any towing operation within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport, or before making each towing flight within such controlled airspace if required by ATC, the pilot in command notifies the control tower. If a control tower does not exist or is not in operation, the pilot in command must notify the FAA flight service station serving that controlled airspace before conducting any towing operations in that airspace; and

* * * * *

40. Section 91.703 is amended by revising paragraph (a)(1) to read as follows:

§ 91.703 Operations of civil aircraft of U.S. registry outside of the United States.

(a) * * *

(1) When over the high seas, comply with annex 2 (Rules of the Air) to the Convention on International Civil Aviation and with §§ 91.117(c), 91.127, 91.129, and 91.131;

* * * * *

41. Section 91.711 is amended by revising paragraph (c)(1)(i) to read as follows:

§ 91.711 Special rules for foreign civil aircraft.

* * * * *

(c) * * *

(1) * * *

(i) Radio equipment allowing two-way radio communication with ATC when it is operated in controlled airspace; and

* * * * *

42. Section 91.905 is amended by adding § 91.126 and revising §§ 91.127, 91.129, 91.130, 91.131, and 91.135 to read as follows:

§ 91.905 List of rules subject to waivers.

* * * * *

91.126 Operating on or in the vicinity of an airport in Class G airspace.
91.127 Operating on or in the vicinity of an airport in Class E airspace.
91.129 Operations in Class D airspace.
91.130 Operations in Class C airspace.
91.131 Operations in Class B airspace.

* * * * *

91.135 Operations in Class A airspace.

* * * * *

43. Appendix D of part 91 is revised to read as follows:

Appendix D—Airports/Locations: Special Operating Restrictions

Section 1. Locations at which the requirements of § 91.215(b)(2) apply.

The requirements of § 91.215(b)(2) apply below 10,000 feet above the surface within a 30-nautical-mile radius of each location in the following list:

Atlanta, GA (The William B. Hartsfield Atlanta International Airport)
Baltimore, MD (Baltimore Washington International Airport)
Boston, MA (General Edward Lawrence Logan International Airport)
Chantilly, VA (Washington Dulles International Airport)
Charlotte, NC (Charlotte/Douglas International Airport)
Chicago, IL Chicago-O'Hare International Airport)
Cleveland, OH (Cleveland-Hopkins International Airport)
Dallas, TX (Dallas/Fort Worth Regional Airport)
Denver, CO (Stapleton International Airport)
Detroit, MI (Metropolitan Wayne County Airport)
Honolulu, HI (Honolulu International Airport)
Houston, TX (Houston Intercontinental Airport)
Kansas City, KS (Mid-Continent International Airport)
Las Vegas, NV (McCarran International Airport)
Los Angeles, CA (Los Angeles International Airport)
Memphis, TN (Memphis International Airport)
Miami, FL (Miami International Airport)
Minneapolis, MN (Minneapolis-St. Paul International Airport)
Newark, NJ (Newark International Airport)
New Orleans, LA (New Orleans International Airport-Moisant Field)
New York, NY (John F. Kennedy International Airport)
New York, NY (LaGuardia Airport)
Orlando, FL (Orlando International Airport)
Philadelphia, PA (Philadelphia International Airport)
Phoenix, AZ (Phoenix Sky Harbor International Airport)
Pittsburgh, PA (Greater Pittsburgh International Airport)
St. Louis, MO (Lambert-St. Louis International Airport)

Salt Lake City, UT (Salt Lake City International Airport)
San Diego, CA (San Diego International Airport)
San Francisco, CA (San Francisco International Airport)
Seattle, WA (Seattle-Tacoma International Airport)
Tampa, FL (Tampa International Airport)
Washington, DC (Washington National Airport)

Section 2. Airports at which the requirements of § 91.215(b)(5)(ii) apply.

The requirements of § 91.215(b)(5)(ii) apply to operations in the vicinity of each of the following airports:

Billings, MT (Logan International Airport)

Section 3. Locations at which Special VFR operations are prohibited.

The Special VFR weather minimums of § 91.157 do not apply to the following airports:

Atlanta, GA (The William B. Hartsfield Atlanta International Airport)
Baltimore, MD (Baltimore/Washington International Airport)
Boston, MA (General Edward Lawrence Logan International Airport)
Buffalo, NY (Greater Buffalo International Airport)
Chicago, IL (Chicago-O'Hare International Airport)
Cleveland, OH (Cleveland-Hopkins International Airport)
Columbus, OH (Port Columbus International Airport)
Covington, KY (Greater Cincinnati International Airport)
Dallas, TX (Dallas/Fort Worth Regional Airport)
Dallas, TX (Love Field)
Denver, CO (Stapleton International Airport)
Detroit, MI (Metropolitan Wayne County Airport)
Honolulu, HI (Honolulu International Airport)
Houston, TX (Houston Intercontinental Airport)
Indianapolis, IN (Indianapolis International Airport)
Los Angeles, CA (Los Angeles International Airport)
Louisville, KY (Standiford Field)
Memphis, TN (Memphis International Airport)
Miami, FL (Miami International Airport)
Minneapolis, MN (Minneapolis-St. Paul International Airport)
Newark, NJ (Newark International Airport)
New York, NY (John F. Kennedy International Airport)
New York, NY (LaGuardia Airport)
New Orleans, LA (New Orleans International Airport-Moisant Field)
Philadelphia, PA (Philadelphia International Airport)
Pittsburgh, PA (Greater Pittsburgh International Airport)
Portland, OR (Portland International Airport)
San Francisco, CA (San Francisco International Airport)
Seattle, WA (Seattle-Tacoma International Airport)
St. Louis, MO (Lambert-St. Louis International Airport)
Tampa, FL (Tampa International Airport)
Washington, DC (Washington National Airport)

Section 4. Locations at which solo student pilot activity is not permitted.

Pursuant to § 91.131(b)(2), solo student pilot operations are not permitted at any of the following airports.

Atlanta, GA (The William B. Hartsfield Atlanta International Airport)
Boston, MA (General Edward Lawrence Logan International Airport)
Chicago, IL (Chicago-O'Hare International Airport)
Dallas, TX (Dallas/Fort Worth Regional Airport)
Los Angeles, CA (Los Angeles International Airport)
Miami, FL (Miami International Airport)
Newark, NJ (Newark International Airport)
New York, NY (John F. Kennedy International Airport)
New York, NY (LaGuardia Airport)
San Francisco, CA (San Francisco International Airport)
Washington, DC (Washington National Airport)
Andrews Air Force Base, MD

PART 93—SPECIAL AIR TRAFFIC RULES AND AIRPORT TRAFFIC PATTERNS

44. The authority citation for part 93 is revised to read as follows:

Authority: 49 U.S.C. app. 1302, 1303, 1348, 1354(a), 1421(a), 1424, 2451 *et seq.* 49 U.S.C. 106(g).

45. Section 93.1 is amended by revising paragraph (b) to read as follows:

§ 93.1 Applicability.

* * * * *

(b) Unless otherwise authorized by ATC, each person operating an aircraft shall do so in accordance with the special air traffic rules in this part in addition to other applicable rules in Part 91 of this chapter.

Subparts I, N, O, Q, and R [Removed and Reserved]

46. Part 93 is amended by removing and reserving subparts I(§§ 93.111–93.113), N(§§ 93.161–93.163), O(§§ 93.171–93.175), Q(§§ 93.195–93.199), and R§§ 93.200–93.208).

47. Section 93.151 is amended by revising the introductory text to read as follows:

§ 93.151 Applicability.

This subpart prescribes special air traffic rules and communications requirements for persons operating aircraft, under VFR, below 2,500 feet MSL within the lateral boundaries of the surface area of the Class E airspace area designated for Ketchikan International Airport, Alaska, excluding that airspace below 600 feet MSL and—

* * * * *

PART 101—MOORED BALLOONS, KITES, UNMANNED ROCKETS AND UNMANNED FREE BALLOONS

48. The authority citation for part 101 is revised to read as follows:

Authority: 49 U.S.C. app. 1348, 1354, 1372, 1421, 1442, 1443, 1472, 1510, and 1522.

49. Section 101.33(a) is revised to read as follows:

§ 101.33 Operating limitations.

* * * * *

(a) Unless otherwise authorized by ATC, below 2,000 feet above the surface within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport;

* * * * *

PART 103—ULTRALIGHT VEHICLES

50. The authority citation for part 103 is revised to read as follows:

Authority: 49 U.S.C. app. 1348, 1354(a), 1421(a), 1422, and 1423; 49 U.S.C. 1655(c).

51.–52. Section 103.17 is revised to read as follows:

§ 103.17 Operations in certain airspace.

No person may operate an ultralight vehicle within Class A, Class B, Class C, or Class D airspace or within the lateral boundaries of the surface area of Class E airspace designated for an airport unless that person has prior authorization from the ATC facility having jurisdiction over that airspace.

53. Section 103.23 is revised to read as follows:

§ 103.23 Flight visibility and cloud clearance requirements.

No person may operate an ultralight vehicle when the flight visibility or distance from clouds is less than that in the table found below. All operations in Class A, Class B, Class C, and Class D airspace or Class E airspace designated for an airport must receive prior ATC authorization as required in § 103.17 of this part.

Airspace	Flight visibility	Distance from clouds
Class A	Not applicable	Not Applicable.
Class B	3 statute miles	Clear of Clouds.
Class C	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.
Class D	3 statute miles	500 feet below. 1,000 feet above. 2,000 feet horizontal.

Airspace	Flight visibility	Distance from clouds
Class E:		
Less than 10,000 feet MSL.	3 statute miles....	500 feet below. 1,000 feet above. 2,000 feet horizontal.
At or above 10,000 feet MSL.	5 statute miles....	1,000 feet below. 1,000 feet above. 1 statute mile horizontal.
Class G:		
1,200 feet or less above the surface (regardless of MSL altitude).	1 statute mile.....	Clear of clouds.
More than 1,200 feet above the surface but less than 10,000 feet MSL.	1 statute mile.....	500 feet below. 1,000 feet above. 2,000 feet horizontal.
More than 1,200 feet above the surface and at or above 10,000 feet MSL.	5 statute miles....	1,000 feet below. 1,000 feet above. 1 statute mile horizontal.

PART 105—PARACHUTE JUMPING

54. The authority citation for part 105 is revised to read as follows:

Authority: 49 U.S.C. App. 1348, 1354, and 1421; 49 U.S.C. 106(g).

55.–56. Section 105.19 is revised to read as follows:

§ 105.19 Jumps in or into Class A, Class B, Class C, and Class D airspace.

(a) No person may make a parachute jump, and no pilot in command may allow a parachute jump to be made from that aircraft, in or into Class A, Class B, Class C, and Class D airspace without, or in violation of, the terms of an ATC authorization issued under this section.

(b) Each request for an authorization under this section must be submitted to the nearest FAA air traffic control facility or FAA flight service station and must include the information prescribed by § 105.25(a).

§ 105.20 [Removed and Reserved]

57. Section 105.20 is removed and reserved.

§ 105.21 [Removed and Reserved]

58. Section 105.21 is removed and reserved.

PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

59. The authority citation for part 121 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355, 1356, 1357, 1401, 1421–1430, 1472, 1485, and 1502; 49 U.S.C. 106(g).

60. Section 121.347 is amended by revising paragraph (a)(2) to read as follows:

§ 121.347 Radio equipment for operations under VFR over routes navigated by pilotage.

(a) * * *

(2) Communicate with appropriate traffic control facilities from any point within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport in which flights are intended.

* * * * *

61. Section 121.649 is amended by revising paragraph (c) to read as follows:

§ 121.649 Takeoff and landing weather minimums: VFR: Domestic air carriers.

* * * * *

(c) The weather minimums in this section do not apply to the VFR operation of fixed-wing aircraft at any of the locations where the special weather minimums of § 91.157 of this chapter are not applicable (See part 91, appendix D, section 3 of this chapter). The basic VFR weather minimums of § 91.155 of this chapter apply at those locations.

PART 127—CERTIFICATION AND OPERATIONS OF SCHEDULED AIR CARRIERS WITH HELICOPTERS

62. The authority citation for part 127 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1421, 1422, 1423, 1424, 1425, 1430; 49 U.S.C. 106(g).

63. Section 127.125 is amended by revising paragraph (b) to read as follows. The introductory text of the section is republished for the convenience of the reader.

§ 127.125 Radio equipment for operations over routes navigated by pilotage.

No person may operate a helicopter over a route that can be navigated by pilotage, unless the helicopter is equipped with the radio equipment needed to perform the following functions under normal operating conditions:

* * * * *

(b) Communicate with ATC towers from any point within the lateral boundaries of the surface areas of Class B, Class D, Class C, or Class D airspace designated for an airport in which flights are intended.

* * * * *

PART 135—AIR TAXI OPERATORS AND COMMERCIAL OPERATORS

64. The authority citation for part 135 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355(a), 1421 through 1431, and 1502; 49 U.S.C. 106(g).

65. Section 135.205 is amended by revising paragraph (b) introductory text to read as follows:

§ 135.205 VFR: Visibility requirements.

* * * * *

(b) No person may operate a helicopter under VFR in Class G airspace at an altitude of 1,200 feet or less above the surface or within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport unless the visibility is at least—

* * * * *

PART 137—AGRICULTURAL AIRCRAFT OPERATIONS

66. The authority citation for part 137 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1348(c), 1421, and 1427.

67. Section 137.43 is revised to read as follows:

§ 137.43 Operations in controlled airspace designated for an airport.

(a) Except for flights to and from a dispensing area, no person may operate an aircraft within the lateral boundaries of the surface area of Class B, Class C, or Class D airspace designated for an airport unless authorization for that operation has been obtained from the ATC facility having jurisdiction over that area.

(b) No person may operate an aircraft in weather conditions below VFR minimums within the lateral boundaries of a Class E airspace area that extends upward from the surface unless authorization for that operation has been obtained from the ATC facility having jurisdiction over that area.

(c) Notwithstanding § 91.157(a)(2) of this chapter, an aircraft may be operated under the special VFR weather minimums without meeting the requirements prescribed therein.

PART 139—CERTIFICATION AND OPERATIONS: LAND AIRPORTS SERVING CERTAIN AIR CARRIERS

68. The authority citation for part 139 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a) and 1432; 49 U.S.C. 106(g).

69. Section 139.323 is amended by revising paragraph (a) to read as follows:

§ 139.323 Traffic and wind direction indicators.

* * * * *

(a) A wind cone that provides surface wind direction information visually to pilots. For each airport in a Class B airspace area, supplemental wind cones must be installed at each runway end or at least at one point visible to the pilot while on final approach and prior to takeoff. If the airport is open for air carrier operations during hours of darkness, the wind direction indicators must be lighted.

* * * * *

PART 171—NON-FEDERAL NAVIGATION FACILITIES

70. The authority citation for part 171 is revised to read as follows:

Authority: 49 U.S.C. app. 1343, 1346, 1348, 1354(a), 1355, 1401, 1421–1430, 1472(c), 1502, and 1522; 49 U.S.C. 106(g).

71. Section 171.9 is amended by revising paragraphs (e)(1) and (e)(2) to read as follows:

§ 171.9 Installation requirements.

* * * * *

(e) * * *

(1) At facilities outside of and not immediately adjacent to controlled airspace, there must be ground-air communications from the airport served by the facility. Separate communications channels are acceptable.

(2) At facilities within or immediately adjacent to controlled airspace, there must be the ground-air communications required by paragraph (e)(1) of this section and reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communication facility. Paragraphs (e) (1) and (2) of this section are not mandatory at airports where an adjacent FAA facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace and where extensive delays are not a factor, the requirements of paragraphs (e) (1) and (2) of this section may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communication facility, if an adjacent FAA facility can communicate with aircraft during the proposed instrument approach procedure, at least down to the minimum en route altitude for the controlled airspace area.

* * * * *

72. Section 171.29 is amended by revising paragraphs (d)(1) and (d)(2) as follows:

§ 171.29 Installation requirements.

* * * * *

(d) * * *

(1) At facilities outside of and not immediately adjacent to controlled airspace, there must be ground-air communications from the airport served by the facility. Voice on the aid controlled from the airport is acceptable.

(2) At facilities within or immediately adjacent to controlled airspace, there must be the ground-air communications required by paragraph (d)(1) of this section and reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communication facility. Paragraphs (d) (1) and (2) of this section are not mandatory at airports where an adjacent FAA facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of paragraphs (d) (1) and (2) of this section may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communications facility, if an adjacent FAA facility can communicate with aircraft during the proposed instrument approach procedure, at least down to the minimum en route altitude for the controlled airspace area.

73. Section 171.49 is amended by revising paragraph (e) to read as follows:

§ 171.49 Installation requirements.

* * * * *

(e) The facility must have, or be supplemented by (depending on the circumstances) the following ground-air or landline communications services:

(1) At facilities outside of and not immediately adjacent to controlled airspace, there must be ground-air communications from the airport served by the facility. The utilization of voice on the ILS frequency should be determined by the facility operator on an individual basis.

(2) At facilities within or immediately adjacent to controlled airspace, there must be the ground-air communications required by paragraph (e)(1) of this section and reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communications facility. Paragraphs (e)(1) and (e)(2) of this section are not mandatory at airports where an adjacent FAA facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of paragraphs (e)(1) and (e)(2) of this section may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communications facility, if an adjacent FAA facility can communicate with aircraft during the proposed instrument approach procedure down to the airport surface or at least to the minimum approach altitude.

74. Section 171.113 is amended by revising paragraph (f) to read as follows:

§ 171.113 Installation requirements.

* * * * *

(f) The facility must have the following ground-air or landline communication services:

(1) At facilities outside of and not immediately adjacent to controlled airspace, there must be ground-air communications from the airport served by the facility. The utilization of voice on the SDF should be determined by the facility operator on an individual basis.

(2) At facilities within or immediately adjacent to controlled airspace, there must be ground/air communications required by paragraph (b)(1) of this section and reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility. Compliance with paragraphs (f) (1) and (2) of this section need not be shown at airports where an adjacent Federal Aviation Administration facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of paragraphs (f) (1) and (2) of this section may be reduced to

reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility, if an adjacent Federal Aviation Administration facility can communicate with aircraft during the proposed instrument approach procedure down to the airport surface or at least down to the minimum approach altitude.

* * * * *

75. Section 171.159 is amended by revising paragraphs (e) (1) and (e)(2) as follows:

§ 171.159 Installation requirements.

* * * * *

(e) * * *

(1) At facilities outside of and not immediately adjacent to controlled airspace, there must be ground-air communications from the airport served by the facility. Separate communications channels are acceptable.

(2) At facilities within or immediately adjacent to controlled airspace, there must be the ground-air communications required by paragraph (e)(1) of this section and reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility. Separate communications channels are acceptable.

Compliance with paragraphs (e) (1) and (2) of this section need not be shown at airports where an adjacent Federal Aviation Administration facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of paragraphs (e) (1) and (2) of this section may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility, if an adjacent Federal Aviation Administration facility can communicate with aircraft during the proposed instrument approach procedure, at least down to the minimum en route altitude for the controlled airspace area.

76. Section 171.209 is amended by revising paragraph (d) to read as follows:

§ 171.209 Installation requirements.

* * * * *

(d) At facilities within or immediately adjacent to controlled airspace and that are intended for use as instrument approach aids for an airport, there must be ground-air communications or reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communication facility. Compliance with this paragraph need not be shown at airports where an adjacent Federal Aviation Administration facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of this paragraph may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility, if an adjacent Federal Aviation Administration facility can communicate with aircraft during the proposed instrument approach procedure, at least down to the minimum en route altitude for the controlled airspace area.

77. Section 171.271 is amended by revising paragraph (e) to read as follows:

§ 171.271 Installation requirements.

(e) The facility must have, or be supplemented by, ground-air or landline communications services. At facilities within or immediately adjacent to controlled airspace and that are intended for use as instrument approach aids for an airport, there must be ground-air communications or reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communication facility. Compliance with this paragraph need not be shown at airports where an adjacent Federal Aviation Administration facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of this paragraph may be reduced to reliable communications (at least a landline telephone) from the airport to the nearest Federal Aviation Administration air traffic control or communications facility, if an adjacent Federal Aviation Administration facility can communicate with aircraft during the proposed instrument approach procedure, at least down to the minimum en route altitude for the controlled area.

* * * * *

78. Section 171.323 is amended by revising paragraph (i) to read as follows:

§ 171.323 Fabrication and installation requirements.

* * * * *

(i) The facility must have, or be supplemented by, ground, air, or landline communications services. At facilities within or immediately adjacent to controlled airspace, that are intended for use as instrument approach aids for an airport, there must be ground air communications or reliable communications (at least a landline telephone) from the airport to the nearest FAA air traffic control or communication facility. Compliance with this paragraph need not be shown at airports where an adjacent FAA facility can communicate with aircraft on the ground at the airport and during the entire proposed instrument approach procedure. In addition, at low traffic density airports within or immediately adjacent to controlled airspace, and where extensive delays are not a factor, the requirements of this paragraph may be reduced to reliable communications from the airport to the nearest FAA air traffic control or communications facility. If the adjacent FAA facility can communicate with aircraft during the proposed instrument approach procedure down to the airport surface or at least down to the minimum en route altitude, this would require at least a landline telephone.

* * * * *

Issued in Washington, DC on November 14, 1991.

James B. Busey,

Administrator.

[FR Doc. 91-29869 Filed 12-12-91; 8:45 am]

BILLING CODE 4910-13-M

federal register

Tuesday
December 17, 1991

Part VI

Department of the Interior

Minerals Management Service

New Alternatives to the Proposed Comprehensive Outer Continental Shelf Natural Gas and Oil Resource Management Program for 1992–1997; Notice of Request for Comments

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Request for Comments on New Alternatives to the Proposed Comprehensive Outer Continental Shelf (OCS) Natural Gas and Oil Resource Management Program for 1992–1997

AGENCY: Minerals Management Service (MMS), Department of the Interior.

SUMMARY: Comments are requested on the alternative of expanding the area proposed for consideration of leasing and the renaming of the planning area for the Proposed OCS Oil and Gas Lease Sale 149, Cook Inlet.

Additionally, comments are requested on the alternative of selecting St. George Basin and Hope Basin as the two areas for leasing consideration among the five lower potential Alaska planning areas being considered in the Proposed Final 5-Year Comprehensive Program (1992–1997).

DATES: Comments and information must be received within 45 days of the publication of this Notice.

ADDRESS: Comments and information on the above alternatives should be mailed to: Director, Minerals Management Service (MS–4230), 1849 C Street, NW., Washington, DC 20240. Hand deliveries to the Department of the Interior may be made at 1849 C Street, NW., room 2525, Washington, DC. Envelopes or packages should be marked "Comments on Proposed 5-Year Comprehensive Program—Cook Inlet, Hope Basin, and St. George Basin Planning Areas." If any privileged or proprietary information which the respondent wishes to be treated as confidential is submitted, the envelope should be marked "Contains Confidential Information." Under section 18(c)(1) of the OCS Lands Act and 30 CFR 256.19(b), any suggestions from the executive of any affected local government in an affected State should also be submitted to the Governor of such State.

FOR FURTHER INFORMATION CONTACT: For information on the above alternatives telephone Paul Stang or Jan Arbegast, Branch of Program Development and Planning, at (202) 208–3072 or Robert Brock, Regional Supervisor, Leasing and Environment, Alaska OCS Region, at (907) 271–6045.

SUPPLEMENTARY INFORMATION: The MMS has received comments on the Proposed 5-Year Comprehensive Program (1992–1997) and the Request for Interest and Comments for the Proposed Oil and Gas Lease Sale 149, Cook Inlet. Several industry commentors requested that the area proposed for consideration of leasing in Cook Inlet be enlarged based on new geologic and geophysical information.

Consequently, as part of the 5-year program, we are considering enlarging the area to be considered for leasing in Cook Inlet to include approximately 761 blocks consisting of approximately 3.7 million acres, but limiting the number of leases which can be issued in lease Sale 149 to 250 or possibly less. Enlargement of the area for consideration of leasing would provide an opportunity for continuing new and innovative analysis of hydrocarbon potential which is important to the discovery of new domestic reserves. Map 1 shows the area included in the Proposed 5-Year Comprehensive Program and the enlarged area now being considered for inclusion in the Proposed Final 5-Year Comprehensive Program.

Based on comments received on, and industry interest in planning areas of, the Proposed Comprehensive Natural Gas and Oil Resource Management Program for 1992–1997, we are considering narrowing the five lower potential Alaskan planning areas (Norton Basin, Navarin Basin, St. Matthew-Hall, Hope Basin, and St. George Basin) to two planning areas, the Hope Basin and St. George Basin, for leasing consideration in the Proposed Final 5-Year Comprehensive Program (1992–1997). The area proposed for leasing consideration in this alternative, the St. George Basin and the Hope Basin, would be as configured in the Proposed Comprehensive Program (1992–1997), announced in the **Federal Register**, Vol. 56, No. 158, on August 1, 1991, and as depicted on Map 2. Sales in these two areas would be proposed for 1994 and 1997, respectively.

Some local area residents have asked that the planning area be renamed Cook Inlet/Shelikof Strait so that it is clear that Shelikof Strait is part of the planning area. The MMS is considering this request.

Additional comments and recommendations were received on the Proposed Comprehensive Program and Draft Environmental Impact Statement announced in the **Federal Register**, Vol. 56, No. 158, on August 1, 1991. A decision on whether to adopt any or all of these recommendations will be made in conjunction with the Department of the Interior's announcement of the Proposed Final Comprehensive Program in spring 1992.

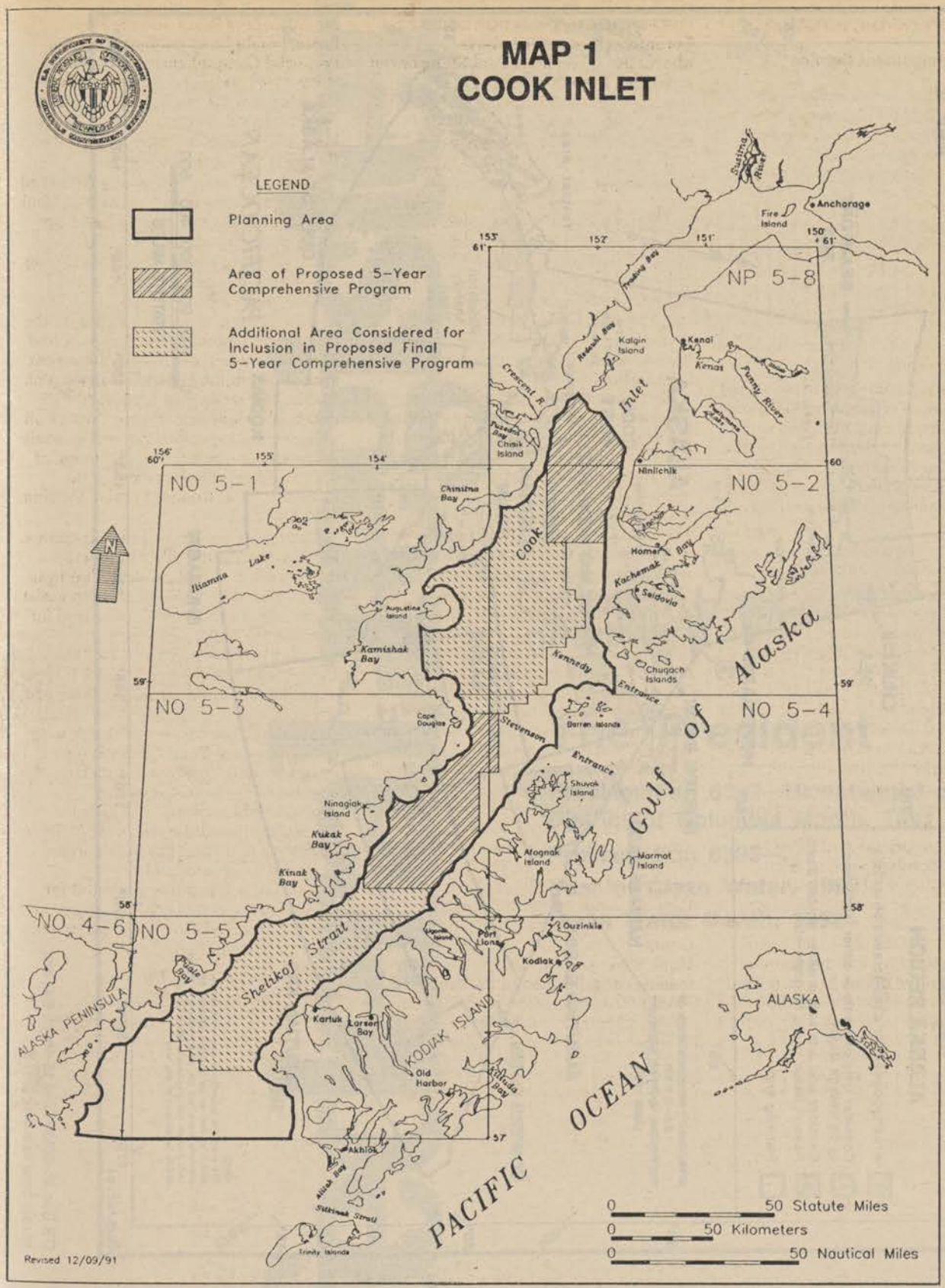
Comments are requested from States, local governments, other interested individuals and groups, the oil and gas industry, and Federal agencies to assist in determining if the area proposed for consideration of leasing for the proposed oil and gas lease Sale 149—Cook Inlet—should be enlarged; if the planning areas should be renamed; and if both the St. George Basin and Hope Basin should be considered for leasing in the Proposed Final Comprehensive Program (1992–1997). In particular, comments are solicited on any geological, biological, or physical characteristics of the areas; potential for discovery of oil and gas in the areas; potential environmental or socioeconomic impacts; potential for effects on the coastal zone if any or all of the alternatives are adopted; or other relevant information.

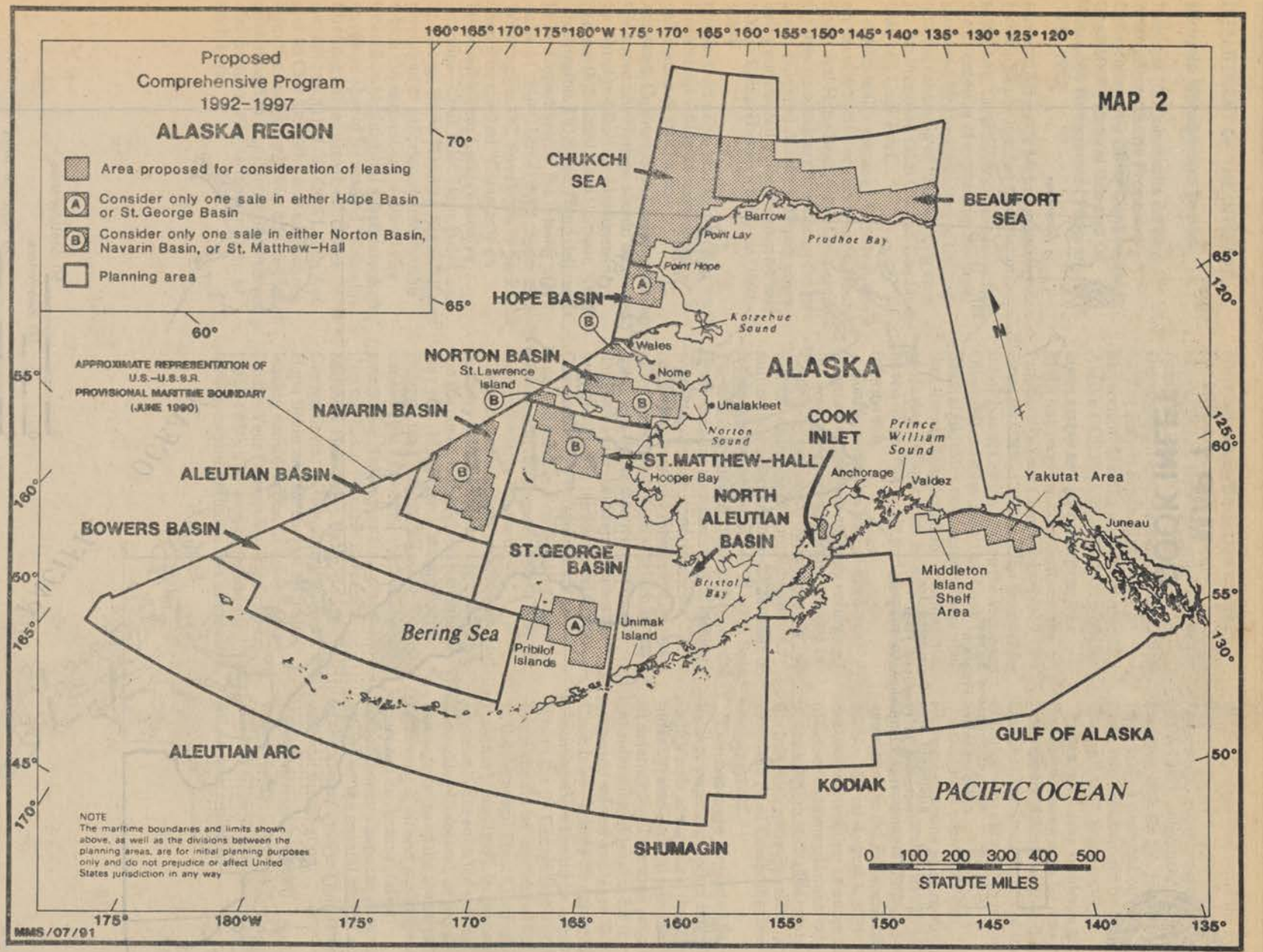
Dated: December 13, 1991.

Scott Sewell,

Director, Minerals Management Service.

BILLING CODE 4310-MR-M


MAP 1
COOK INLET
LEGEND
Planning Area
Area of Proposed 5-Year Comprehensive Program
Additional Area Considered for Inclusion in Proposed Final 5-Year Comprehensive Program
NP 5-8
NO 5-1
NO 5-2
NO 5-3
NO 5-4
NO 4-6
NO 5-5
Anchorage
Fire Island
Kalgin Island
Kenai
Kenai River
Kasilof River
Ninilchik
Homer
Kachemak Bay
Seldovia
Chugach Islands
Kennedy Entrance
Barren Islands
Shuyak Island
Afognak Island
Marmot Island
Ouzinkie
Kodiak
Port Lions
Chisik Island
Chinitna Bay
Iliamna Lake
Augustine Island
Kamishak Bay
Cape Douglas
Stevenson Entrance
Ninagiak Island
Kukak Bay
Kinak Bay
Cook Inlet
Gulf of Alaska
Shelikof Strait
ALASKA PENINSULA
KODIAK ISLAND
Kartuk
Larsen Bay
Old Harbor
Akhiok
Alitak Bay
Sitkinak Strait
Trinity Islands
PACIFIC OCEAN
ALASKA
0 50 Statute Miles
0 50 Kilometers
0 50 Nautical Miles
Revised 12/09/91



[FR Doc. 91–30156 Filed 12–16–91; 8:45 am]

BILLING CODE 4310–MR–C

federal register

Tuesday
December 17, 1991

Part VII

The President

Proclamation 6392—Bicentennial of the District of Columbia Month, 1991

Proclamation 6393—
Year of Clean Water, 1992
Clean Water Month, 1992

Digital Edition

Federal Register
Vol. 56, No. 242
Tuesday, December 17, 1991

Presidential Documents

Title 3—

The President

Proclamation 6392 of December 13, 1991

Bicentennial of the District of Columbia Month, 1991

By the President of the United States of America

A Proclamation

Although it encompasses just 10 square miles, the District of Columbia contains a vast wealth of history and culture—a legacy that befits our Nation's Capital. This year, we celebrate the 200th anniversary of our remarkable Federal city.

Conceived by the Framers of our Constitution, who provided for the establishment of a special district to serve "as the Seat of the Government of the United States," our Nation's Capital began to take shape in 1791. In January of that year, a site was selected for the city under the direction of President George Washington. The following month Andrew Ellicot and Benjamin Banneker, a successful black farmer who was self-taught in engineering, mathematics, and other fields, began to survey the terrain.

Plans for the actual layout of the city reflected the exuberance, pride, and optimism of our young Republic. When he submitted his design to the Congress in December 1791, Major Pierre L'Enfant included numerous provisions for parks, fountains, and wide, sweeping avenues—all reflecting a vision as grand and as ambitious as the American experiment itself.

Over the years, a number of our Nation's leaders took great personal interest in the development of the Federal city. Thomas Jefferson offered advice and sketches for its design, and it was his idea to build a large mall extending from the foot of the hill on which our magnificent United States Capitol now stands. Today the Mall in Washington is surrounded by monuments and museums that honor the brilliant thinkers and brave heroes who have defined and defended the American ideals of liberty and self-government. Many of the museums in our Nation's Capital also contain vast collections of American art and folklore, as well as fascinating displays of U.S. achievements in science, industry, and aviation.

As the seat of government of the United States for 200 years, our Nation's Capital has become a center of American culture and a world-renowned symbol of freedom and democracy. Here is where President John Adams and his successors continued the work that President George Washington and the First Congress had begun in New York. Here is where President Abraham Lincoln labored to preserve our Union; and here is where the Reverend Dr. Martin Luther King, Jr., led the historic march that energized the civil rights movement and reminded America of its promise of liberty and justice for all. Much of our Nation's history has marched through Washington, D.C., and today that journey continues as we engage in the day-to-day process of democratic government.

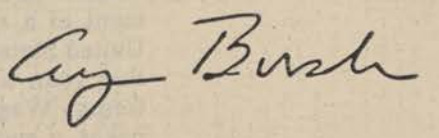
While our Nation's Capital belongs to all Americans, this occasion is a very special one for the residents of the District of Columbia. Many families have lived in the city for generations, and this bicentennial is also a celebration of their roots.

At the end of the Civil War, thousands of African Americans came to Washington, making the city a virtual symbol of emancipation and progress. Their accomplishments, reflected in the growth of institutions such as Howard University, helped pave the way for countless others. Today residents of the District of Columbia continue to make outstanding contributions in education, business, science, and the arts. On this occasion, all Americans join them in celebrating 200 years of history and achievement.

The Congress, by House Joint Resolution 356, has designated December 1991 as "Bicentennial of the District of Columbia Month" and has authorized and requested the President to issue a proclamation in observance of this month.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim December 1991 as Bicentennial of the District of Columbia Month. I invite all Americans to observe this month with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of December, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.



[FR Doc. 91-30290
Filed 12-16-91; 11:31 am]
Billing code 3195-01-M

Presidential Documents

Proclamation 6393 of December 13, 1991

Year of Clean Water, 1992

Clean Water Month, 1992

By the President of the United States of America

A Proclamation

Water is essential to every form of life on Earth. Indeed, this vital substance unites our planet's ecosystems, the miraculous yet fragile relationships in nature that sustain each other as well as all human activity. Recognizing the importance of our precious water resources, the United States has made a firm commitment to protecting their physical, chemical, and biological integrity. This year, the 20th anniversary of the Clean Water Act reminds us that we are all stewards of our water resources, and, as such, we are responsible for their preservation and wise use.

Since the enactment of the Clean Water Act in 1972, we have achieved remarkable improvements in many of our Nation's water resources. Twenty years ago, less than half of America's rivers supported fish and shellfish or provided wildlife habitat. Fishing and swimming were restricted in many areas, and drinking water supplies were threatened. Today, however, nearly three-fourths of the Nation's waters support these uses, and many others have significantly improved in quality. Fish and waterfowl have returned to many of our rivers, lakes, and coastal waters.

We have taken great strides during the past two decades, primarily by controlling pollution from sewage treatment plants and industrial facilities. Recent advances in science and technology have enabled us to engage in more effective studies of water pollution—its causes and its effects. These studies, which have often revealed the magnitude of previously underestimated problems, have led to more vigorous and innovative antipollution measures. At the same time, public awareness of the importance of clean water has also increased; now there is more support than ever for protecting and enhancing water quality.

While we can take pride in this progress, many challenges remain. Urban and industrial growth are creating additional sources of pollution while placing increased demands on limited water resources. Contaminated runoff from farmlands as well as city streets is, all too often, degrading our waters and damaging ecosystems. Scientists continue to detect unacceptable levels of pollutants in many bodies of water and in the tissues of finfish and shellfish. All Americans must continue to work together to protect our water resources and the wildlife that depends on them.

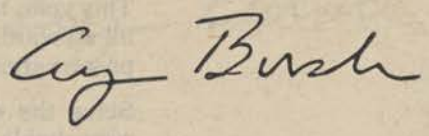
We have already discerned the need for new and innovative solutions. Indeed, today we know that the health of aquatic ecosystems must be examined holistically, to determine how various forms of human activity affect water quality. We know that we must protect entire watersheds that feed into our rivers, lakes, and coastal waters. We also recognize that, by preventing pollution at the source, we can protect watersheds and avoid the high economic and environmental costs of treating wastes and restoring ecosystems after pollution has already occurred. Moreover, experience has shown us that our actions must be based on sound science.

The 20th anniversary of the Clean Water Act marks an important milestone in the history of American environmental protection. However, just as water links each of our planet's ecosystems, water pollution recognizes no boundaries. All Americans and their representatives in all levels of government must work together to promote wise stewardship of this, our "water planet." We must also foster greater cooperation in the international community.

As an expression of our national commitment to these goals, the Congress, by Public Law 101–424, has designated 1992 as the "Year of Clean Water" and October 1992 as "Clean Water Month."

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim 1992 as the Year of Clean Water and October 1992 as Clean Water Month. I call upon all Americans to observe this year and month with appropriate programs, ceremonies, and activities. I also ask my fellow Americans to join in setting examples of environmental stewardship in our daily lives.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of December, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.



[FR Doc. 91–30291
Filed 12–16–91; 11:34 am]
Billing code 3195–01–M

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H.R. 3881/Pub. L. 102-225

To expand the boundaries of Stones River National Battlefield, Tennessee, and for other purposes. (Dec. 11, 1991; 105 Stat. 1682; 3 pages) Price: $1.00

H.R. 2105/Pub. L. 102-226

To designate an area as the "Myrtle Foester Whitmire Division of the Aransas National Wildlife Refuge". (Dec. 11, 1991; 105 Stat. 1685; 1 page) Price: $1.00

H.R. 3909/Pub. L. 102-227

Tax Extension Act of 1991. (Dec. 11, 1991; 105 Stat. 1686; 5 pages) Price: $1.00

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